US PATENT APPLICATION
Docket No. WILB01

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS & INTERFERENCES

Application of: BRIAN R. WILL

Serial No. 10/608408 Examiner: Shay
Filed: June 27, 2003 Group Art Unit: 3739

For: EYE FIXATION APPARATUS

Date: October 22, 2007

BRIEF OF THE APPELLANT

REAL PARTY IN INTEREST

Applicant, Brian Will, is the real party in interest to this appeal.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences related to the instant appeal.

STATUS OF CLAIMS

Claims 1-22 are pending.

Prior to this Response, a Final Office Action rejecting all claims was mailed April 11, 2007, responding to Applicant's RCE which included an affidavit submission under 37 C.F.R. 1.132 and adding new claim 22, dated January 12, 2007. The prior final rejection was withdrawn and a new rejection entered by Examiner. Applicant timely filed a Notice of Appeal with applicable fees on June 22, 2007.

Claims 1-22 were rejected under § 112 second paragraph for indefiniteness. .Claims 1-13 were rejected for the first time under § 112.

Claims 1, 11, and 12 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over EP 0372127A1 to L'Esperance or US 6,042,594 to Hellenkamp.

Claims 2 and 13 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 4,173,980 to Curtin.

Claims 3, 4, 7, 8, 14-16, 18, and 19 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkampf in combination with Curtin or Clark et al.

Claims 5, 6, 9, 10, 17-22 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with Curtin and Clark et al, and further in combination with US 5,613,061 to Olson.

STATUS OF AMENDMENTS.

Claims 1-21 are original. Claims 14-21 were previously amended. Claim 22 was presented in the prior RCE. No claims have been added or amended since the final rejection by Examiner. The claims are reproduced in the appendix to this brief.

SUMMARY OF CLAIMED SUBJECT MATTER.

The present invention relates generally to devices and methods for fixating eyes for ophthalmic surgery, and more particularly to eye fixation devices and methods using vacuum pressure for fixation for guiding a surgical tool or laser.

Claims 1-10 relate to a novel apparatus for fixating the eye. The apparatus is convex, matching the convex profile of the cornea. The interior eye-fixation part of the apparatus includes a convex contact surface for contacting the surface of the eyeball encircling the cornea. The eye fixation portion includes a convex contact portion which encircles the cornea, contacting the corneal surface via the lands between criss-cross vacuum distribution channels. A vacuum port is provided in communication with the criss-crossing channels to draw the eyeball membrane to the channels.

Claims 2-9 depend from claim 1. Claim 2 includes adjustment arms which allow the surgeon to use both hands to adjust the eye fixation device in relation to the eyeball before applying vacuum.

Claims 3, 4, 7 and 8 include first and second annular translation guide members with translation rods and adjustment knobs, allowing the surgeon to adjust the annular opening laterally to one another (e.g. in a perpendicular X-Y direction), which is what receives surgical instruments or allows application of a surgical laser, after applying vacuum to fix the fixation apparatus to the eyeball. The threaded guide rods allow micron-level adjustment of position to fine tune the initial positioning of the device.

Claims 5, 6, 9, and 10 include docking screws through the first and second annular translation guide members so that surgical devices, such as laser sighting cones, can be inserted and locked into the annular opening, thereby fixing the surgical devices to the eyeball rather than the eyeball being forced to align with the devices.

Claim 22 incorporates the limitations of Claims 1-10 and explicitly recites a narrow profile which fits under a patient's lid without need for a lid speculum.

Claims 11-21 recite methods for using the novel apparatus of claims 1-10 to provide fixation of the eyeball during ophthalmic surgeries. Claim 12 includes the step of verifying the centering of the eye fixation apparatus and adjusting if necessary by shutting off vacuum, recentering the device, and re-applying vacuum pressure.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-22 are invalid under 35 U.S.C. § 112 second paragraph.

2. Whether claims 1, 11 and 12 are unpatentable under 35 U.S.C. § 103(a) over EP 0372127A1 to L'Esperance or 6,042,594 to Hellenkamp.

3. Whether claims 2 and 13 are unpatentable under 35 U.S.C. § 103(a) over L'Esperance or Hellenkamp, in combination with US 4,173,980 to Curtin.

4. Whether Claims 3, 4, 7, 8, 14, 15, 18, and 19 are unpatentable under § 103(a) over L'Esperance or Hellenkamp in combination with Curtin and/or Clark et al, and further in view of Ruiz.

5. Whether Claims 5, 6, 9, 10, 16, 17, 18 and 19 are unpatentable under § 103(a) over L'Esperance or Hellenkamp, in combination with Curtin and/or Clark et al, and further in combination with US 5,613,061 to Olson.

6. Whether claim 22 is unpatentable under § 103(a) over L'Esperance or Hellenkamp, in combination with Curtin and/or Clark et al, and further in combination with US 5,613,061 to Olson.

7. Whether claims 11-21 are unpatentable under § 103(a) over L'Esperance or Hellenkamp, in combination with Curtin and/or Clark et al, and/or Ruiz and/or Olson.

ARGUMENT

Applicant asserts the subject matter claimed is patentable over the references cited and respectfully requests reversal of the Examiner's rejections. Applicant throughout this Brief refers to Examiner's final rejections in his April 11, 2007 Office Action, as well as Examiner's prior rejections in his July 14, 2006, as the April 11 Office Action in large part reiterated the Examiner's prior rejections.

THE SECTION 112 REJECTION

A. Claims 1-22: The term "convex" is clearly understood.

Examiner rejected claims 1-22 under § 112 second paragraph stating that Applicant has misused the term "convex." As an initial matter, Examiner never raised issue with this term in the prosecution of the application until after Applicant's submission of the RCE with accompanying amendment, so Applicant submits the use of the term is clearly understood. Examiner's dictionary definition of "convex" is correct, but the issue raised by Examiner is simply one of orientation – a convex surface may be considered concave from the reverse perspective so they are not mutually exclusive. The eyeball is essentially a ball – not perfectly spherical – i.e. convex. The eye fixation apparatus described in the application includes an "annular convex bottom contact

portion" – i.e. annular to include an opening for access by a surgeon, and convex to match the convex contours of the eyeball. It necessarily follows that the inside of a convex annulus will be concave – it is merely a matter of reference point. So reference to convex in this context, with reference to an eyeball, the Specification, the drawings, and the knowledge of a person of ordinary skill in the art, obviously would understand that one could refer to the overall shape as convex or concave and render the same meaning. As the Examiner has never before raised this issue and has exchanged numerous discourses with Applicant via office actions without confusion, Applicant submits that "convex" as used in the Specification, Drawings and Claims is clear.

B. <u>Claim 22: "Low profile" is clearly understood.</u>

Examiner rejected claim 22 under § 112 second paragraph stating that "low profile" is unclear as the total height of the device, including the X-Y translation guide members, would be too high to fit under an eyelid. Applicant submits the Examiner misreads the claim. It is the "eye fixation portion" which specifically includes the "low profile... substantially narrow so as to fit under the eye lid of a patient without the use of a lid speculum." Clearly Applicant is not claiming that the entire device fits under a patient's eyelid, but merely the portion extending outward with the criss-cross vacuum channels. Examiner's reference to Fig. 4 ignores the fact that such drawings and figures are not to scale but are necessarily distorted to enable reference to particular features. The Examiner's measurements of the figures provided is therefore inappropriate.

The need for a lid speculum is obviated in the present invention because the vacuum channel portion, which is what grips the surface of the eyeball, does not require a hollow annulus above that portion in order to distribute vacuum along the surface area contacting the eye. This allows the eyelids to close to a degree over this thin lip, shown as # 14, in Fig. 4. The central open portion of the annulus which provides the access for

surgical instruments and additional elements such as the translation guide members and docking screws, is sized to accept the surgical apparatus – which is essentially fixed. Prior art devices, such as L'Esperance (*see Fig. 1*), Hellenkamp (*see Fig. 2*) and Curtin (*see Fig. 2*), cited by Examiner under 103(a) rejections, require a vertical vacuum annulus over the contact area as well as the central vertical annulus providing surgical access. It is this vacuum annulus of prior art devices which is eliminated by the use of criss-cross channels which can extend laterally through a thin extending lip. Applicant made this clear through the Specification, and more so through his affidavit which described in detail the problems caused by prior art devices and how the present invention solves these problems through the use of low profile criss-cross channels.

Antecedent bases are provided in the original specification

(1) at p. 3 ll. 8-10 describing the need for a "low profile fit[ting] comfortably under the eye lid;

(2) at p. 4 ll. 12-14 describing an advantage of the present device as being low profile and not requiring need for a lid speculum, thereby distinguishing the present invention from existing devices.

Section 112 paragraph 2 requires the claims to be sufficiently clear to enable a person to understand, in light of the Specification and Drawings, what the applicant regards as the invention. This does not impose a requirement to provide detailed dimensions, but allows the use of relative dimensions or references, so long as they are adequately clear. The use of language such as "substantially narrow" in relation to a reference which provides basis by which a person of ordinary skill in the art can understand the structure as in "so as to fit under the eye lid of a patient without the use of a lid speculum" is sufficiently clear. *See* Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986) ("A decision on whether a claim is invalid

under § 112, 2d ¶, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.") Applicant submits that the claim, read in light of the specification and drawings, with the knowledge of a person of ordinary skill in the art, is clear and definite and has proper antecedent basis.

THE SECTION 103(A) OBVIOUSNESS REJECTIONS

The standard under Section 103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In re O'Farrell, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l v. Teleflex, Inc., 127 S.Ct. 1727, 1742, 167 L.Ed.2d 705 (2007). The Examiner bears the initial burden in the case of Section 103(a) obviousness rejection which requires the Examiner to put forward evidence that the invention as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention. In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) , citing In re Warner, 379 F.2d 1011, 1016 (CCPA 1967). Where the Examiner relies on a single prior art reference for an obviousness rejection, which does not describe every limitation of the claim, the Examiner must demonstrate how a person of ordinary skill in the art would have been motivated to modify the reference to achieve the invention without the benefit of hindsight, just as with a combination of references.

Where an Applicant submits evidence an Examiner cannot simply deny such evidence without citation to reference of submission of an affidavit himself detailing the bases of his knowledge and expertise. MPEP 2142; In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997). Although the Supreme Court rejected rigid application of the "suggestion, motivation, teaching test" applied by courts in the past, it can still be a

useful starting point for evaluation and to prevent hindsight analysis, so long as it is not applied rigidly and the evaluator maintains the framework of the analysis laid down in Graham v. John Deere Co., 383 U.S. 1 (1966). KSR, 127 S.Ct. at 1242. Moreover, the Examiner cannot rely on the applicant's disclosure in any way in making this prima facie case. MPEP 2143. The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. at 17-18; Miles Lab., Inc. v. Shandon Inc., 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness. Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 231, 236 (Fed. Cir. 1983). Each obviousness determination rests on its own facts. In re Durden, 226 USPQ 359, 361 (Fed. Cir. 1985).

"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986). Here, the Examiner relies upon conclusory statements that combining the references "would be obvious to one of ordinary skill in the art." The Examiner thus failed to establish a *prima facie* case of obviousness to support rejection.

Further, regarding all of the § 103(a) rejections, the Examiner failed to make specific findings as to the level of ordinary skill and the differences between the prior art and the claimed invention.

The difference between the prior art and the invention is exactly that which is claimed and pointed out in the present application. Prior art solutions to the problem of fixing a patient's eyeball . The present invention solves these problems.

A. <u>The Section 103(a) Rejection of Claims 1, 11 and 12 over L'Esperance or Hellenkamp</u>

The Examiner rejected Claim 1, 11 and 12 as unpatentable over L'Esperance or Hellenkamp. Applicant respectfully submits the Examiner erred. None of the references cited by Examiner teach, suggest, or disclose in any way the use of criss-crossing channels to apply vacuum. Thus, Examiner has not even presented a *prima facie* case of obviousness. Nor has Examiner cited any basis for the conclusion that a person of ordinary skill in the art would seek to modify the cited references to eliminate the vacuum annulus designs of the references, other than to argue that the prior art works just as well as Applicant's invention. This is in spite of the Affidavit of Dr. Will providing detailed recitations of the problems caused by prior art devices such as those described by L'Esperance and Hellenkamp. The Examiner provides nothing to bridge the critical gap between the use of a hollow vacuum annulus and the use of criss-crossing vacuum channels other than simply disbelieving Dr. Will's extensive affidavit addressing the differences between the claims and the cited references.

Claims 1, 11 and 12 includes the express structural and functional limitation of criss-crossing vacuum channels. All the limitations of a claim must be considered when weighing the differences between the claimed invention and the prior art in determining the obviousness of a process or method claim. MPEP 2116.01; MPEP § 2143.03. Interpreting the claimed invention as a whole requires consideration of all claim limitations. MPEP 2116.01 To establish *prima facie* obviousness of a claimed invention, all the claim limitations as a whole must be obvious to a person of ordinary skill in the art. "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP 2143.03 (quoting <u>In re Wilson</u>, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)). Functional limitations must be given patentable weight,

even if it is only these limitations which distinguish over prior art. DONNER at 479; In re Land, 368 F.2d 866, 151 USPQ 621 (C.C.P.A. 1966); In re Ludtke, 441 F.2d 660, 169 USPQ 563, 566 (C.C.P.A. 1971); In re Atwood, 354 F.2d 365, 148 USPQ 203, 210 (C.C.P.A. 1966); In re Chiang, Civ. App. No. 94-1144 (Fed. Cir. Nov. 23, 1994) (unpub.); In re Weiss, 26 USPQ 2d 1885 (Fed. Cir. 1993) (unpub.).

Examiner states that both L'Esperance and Hellenkamp teach the device as claimed "except for the criss-cross channels" and use of such channels is obvious because "this is another configuration that would serve to distribute vacuum and thus provides no unexpected results." The Examiner went on to say that to "discontinue the vacuum and reposition the apparatus" is also obvious. With all do respect, this is the epitome of hindsight and requires the Examiner to completely disregard the Applicant's affidavit. Applicant explained, in detail, based upon years of experience and thousands of procedures, and a thorough knowledge of prior art devices, that apparatus using the annular vacuum rings of Hellenkamp or the annular chamber and porous membrane of L'Esperence, prevent the discontinuance of vacuum and repositioning of the fixation apparatus. The Examiner simply discounted the Applicants submission without citation to any reference nor any affidavit by the Examiner.

The references L'Esperance and Hellenkamp do not disclose the combinations of elements recited in independent Claims 1, 11 and 12, nor has any reference been asserted teaching or suggesting such modification, and therefore the Examiner has not established a *prima facie* case of obviousness. None of the references discloses apparatus or methods for an eye fixation apparatus utilizing *criss-crossing channels* on a convex bottom contact portion, without use of a vacuum annulus, nor do they disclose apparatus or methods capable of repositioning a vacuum-based eye fixation apparatus after vacuum has been applied initially. In fact, none of the references cited by

Examiner disclose use of criss-cross channels at all. It is the use of criss-cross channels which primarily distinguishes claims 1, 11 and 12 over Examiner's cited references.

The Examiner provides no basis for disputing Applicant's description of the cited references' weaknesses, other than to argue that the prior art patents are "presumed valid" so Applicant's invention cannot be an unobvious advance. Applicant has never argued that Examiner's references are invalid, merely that they do not address or solve the problems solved by Applicant's inventions. Reference to Dr. Brian Will's Affidavit provides explanation of the unique features of the present invention, and the significant differences from the prior art cited by the Examiner. Nowhere does the Examiner cite any reference upon which to base his conclusory statements that Dr. Will is incorrect, or that prior art devices work so well that no subsequent improvements in the art are necessary.

L'Esperance discloses a method and apparatus for modulating the flux distribution onto a surface to be profiled of an ablative radiation beam, including a fixation device which uses a porous membrane backed by a hollow vacuum annulus. *See L'Esperance, Fig. 1 and col. 4, ll. 28-34* (describing "a hollow annulus.") L'Esperance does not focus on the fixation apparatus but rather on the laser ablation apparatus and methods, especially lensing methods. The description of the fixation means is simply a "hollow annulus, having a convergent axial end wall 11 of air-permeable material contoured to engage and retain an eye via a scleral-corneal region."

L'Esperance does not disclose using criss-cross channels for distributing vacuum, nor any means for fixation not requiring "a hollow annulus." L'Esperance does not even address the problems of scleral damage caused by vacuum fixation devices. Therefore, L'Esperance does not render Applicant's solution obvious.

The Hellenkamp reference, cited by Examiner, specifically discusses the problem

of mucus accumulation which can occlude vacuum components, during procedures and after hardening, and which requires special cleaning procedures to remove. *See Affidavit of Dr. Will ¶ 5.h.* The removable vacuum member in Hellenkamp is specifically intended as an attempt to address this problem, among others, but it is an incomplete solution at best. *See Hellenkamp, col. 5, ll. 43-5.* Examiner states in his last Office Action, "Applicant then states the 'criss-cross channels, providing alternating lands grooves, are fundamental to the present invention', however, there has been no showing of the criticality of this particular arrangement of voids and barriers." *OA April 11, 2007 at p.10.* Applicant submits that this is the focus of much of the application itself – indeed it is one of the stated advantages over existing devices. Moreover, the affidavit of Dr. Will discusses the differences, and resulting advantages, of his criss-cross channels over existing devices such as L'Esperance and Hellenkamp in detail.

Hellenkamp discloses an eye fixation apparatus utilizing an annular hollow vacuum ring with a vacuum ring insert to prevent complete occlusion of vacuum caused by chemosis or buildup of mucous in the vacuum ring. The vacuum ring insert simply is intended to prevent complete occlusion, not prevent damage such as chemosis. *Hellenkamp col. 5 ll. 25-30* ("to maintain the suction channel evacuated even in the presence of chemosis"). Thus Hellenkamp does not solve the problem of chemosis and damage, it merely attempts to deal with the problem as it relates to loss of vacuum. Hellenkamp, however, acknowledges that damage does occur from the operation of annular vacuum rings.

The Examiner states, "Both L'Esperance (EP '127) and Hellenkamp teach a device and method as claimed except for the criss-cross passages." *OA July 14, 2006, at page 5.* The criss-cross channels, providing alternating lands and grooves, are fundamental to the present invention, and are not disclosed by the cited references.

L'Esperance and Hellenkamp do not disclose means for fixing an eye for surgery other than a hollow annulus. A hollow annulus has specific disadvantages not appreciated by either L'Esperance nor Hellenkamp which are addressed by the present invention, as pointed out by the accompanying Affidavit of Dr. Will.

The Examiner also asserts that "to discontinue vacuum and reposition the apparatus if it is not centered on the cornea [is obvious], since proper positioning of the corneal flap is critical..." *OA July 14, 2006, at p. 5.* This simply misses the point. The apparatus and methods of the references cited by the Examiner actually *prevent* discontinuation of vacuum and repositioning of the apparatus due to the negative effects of using a hollow annulus to apply vacuum, as explained by the Affidavit of Dr. Will. Thus, the Examiner's arguments regarding obviousness actually demonstrate the unobviousness of using a system of criss-cross channels providing alternating lands and grooves. In addition, L'Esperance and Hellenkamp retain the significant disadvantage that they require lid speculum during most procedures (due to the inherently high profile of the hollow annulus), especially for patients with narrow ocular orbits, and they contain no teachings to indicate a solution. Other disadvantages of the L'Esperance and Hellenkamp references, which are addressed by the present invention, are made apparent by the accompanying Affidavit of Dr. Will.

Examiner's rejections appear to based on a view that the Applicant is required to prove that the references cited by Examiner are non-functioning, or that such references must be presumed full proof and without significant drawbacks, in order to claim an invention with improved results over the existing art. The burden lies with the Examiner to demonstrate that Applicant's invention is obvious through citation to record evidence rather than simply relying on conclusory statements that he is "unconvinced." In Examiner's Office Action of June 14, 2007, at p.8, Examiner states that because

L'Esperance and other references are patents they are "presumed valid" and therefore L'Esperance's porous membrane does not clog. Respectfully, Examiner misapprehends the difference between patent validity and perfection. The mere fact that a patent is presumed valid does not imply that such a patent solves, perfectly and forever more, all problems associated with the field of art such that no new patentable device may ever issue in the future.

The Examiner cites an article that he interprets as establishing a single cause of "dry eye" after LASIK procedures which would somehow render Applicant's invention superfluous. The Examiner failed to review the references cited by Dr. Will in their entirety, relying only on the abstracts for his conclusory statements. Needless to say, there is likely more than one cause of "dry eye" after LASIK, and Dr. Will is not required to disprove the Examiner's thesis in order to establish that his invention reduces potential for this complication, and that a potential source of the complication is damaged sclera caused by conventional vacuum rings. A copy of the Albietz reference cited by Dr. Will is provided with this Brief in the Evidence Appendix. The purpose of the reference is to demonstrate that problems do exist with existing annular vacuum ring designs such as Hellenkamp.

Examiner referenced an article by Benitez-del-Castillo et al, *Decrease in Tear Secretion and Corneal Sensitivity After Laser In Situ Keratomieusis*, CORNEA, vol. 20(1), January 2001 at pp. 30-32 (*see June 14, 2007 OA at pp.7-8*). The reference, a copy of which was provided by Examiner, does not profess to answer the causes of dry eye complications after LASIK , it merely confirms that such complications do indeed occur. Applicant's invention, as explained in the Specification and in Dr. Will's affidavit, seeks to address some of the causes of complications and less than optimal outcomes. Examiner's article reference does not obviate the different approach that Applicant has

taken to solve these problems.

The difficulty in cleaning is discussed as a general hindrance which can reduce the patient turnover rate. *See Hellenkamp, col. 3, l. 45 – col. 4, l. 12.* The same difficulties with clogging and effective cleaning described in Hellenkamp are magnified in a porous membrane as taught by L'Esperance. Additional drawbacks include higher risk of patient cross-contamination with viral, bacterial and prion material. *See Affidavit of Dr. Will ¶ 5.h.* The present invention provides a relatively smooth and impermeable surface with shallow cross-connected channels which are easily cleaned using conventional methods, thereby extending the life of the apparatus. The cross-connection prevents loss of vacuum from occlusion of any single channel due to buildup.

Additionally, the hollow annulus designs inherent to L'Esperance and Hellenkamp require the use of a lid speculum on patients with narrow ocular orbits. The use of lid specula causes undesired negative side effects which have been documented, and are an ever increasing problem as procedures such as LASIK become more widespread. Dr. Will's Affidavit specifically addresses the complications caused by conventional hollow annulus apparatus. The use of criss-cross channels with alternating lands and grooves in the present invention avoids the need for lid speculum even in patients with narrow orbits because it allows a lower profile device. The Examiner has failed to point to any reference which teaches criss-cross vacuum channels, creating a low profile apparatus which can fit underneath the eyelids, obviating the need for a lid speculum during surgery. All of the art cited by Examiner relies upon an annular design necessitating a vault, with the exception of Ruiz, newly asserted by Examiner, which does not teach the use of a vacuum fixation apparatus at all and so does not support the rejection.

Applicant does not argue that the prior art cited lacks utility or is non-functional,

but the present invention provides unobvious improvements over the cited references which achieve greater accuracy and less discomfort from patients, while making laser keratome procedures more economical for practitioners.

Further, if the Examiner relies on personal knowledge to assert that:

(1) L'Esperance and Hellenkamp are not subject to clogging or occlusion;

(2) neither L'Esperance nor Hellenkamp cause damage to the cornea/conjunctiva surface when vacuum is applied and removed; and,

(3) that use of high profile hollow annular rings as taught by the Examiner's cited references does not cause complications and discomfort to patients;

then the Examiner is required to provide an affidavit explaining the basis of such knowledge. *See* MPEP 2144.03(A) [R-1], which states:

> "It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained that, "as an administrative tribunal the Board clearly has expertise in the subject matter over which it exercises jurisdiction," it made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." *Id.* at 1385-86, 59 USPQ2d at 1697. As the court held in *Zurko*, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Id.* at 1385, 59 USPQ2d at 1697. See also *In re Lee*, 277 F.3d 1338, 1344-45, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002) (In reversing the Board's decision, the court stated "'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation... The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies."

Further, "While 'official notice' may be relied on, these circumstances should be rare when an application is under final rejection..." MPEP 2144.03(A) [R-1].

> "It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. See also *In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979)"

MPEP 2144.03(A) (emphasis original). "If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. *See* 37 C.F.R. 1.104(d)(2)." MPEP 2144.03(C) [R-1]. Furthermore, Section 103 requires analysis of a claimed invention as a whole:

> "Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness."

The Gillette Co. v. S.C. Johnson & Son Inc., 16 USPQ2d 1923 (Fed. Cir. 1990).

The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. at 17-18; Miles Lab., Inc. v. Shandon Inc., 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). The Affidavit of Dr. Will accompanying this RCE provides objective evidence of the difference between the prior art and the claimed invention which must be credited. Regarding the use of criss-cross channels, incorporated into all claims through independent claims 1, 11 and 22, no references cited by the Examiner include criss-cross channels. The use of criss-cross channels minimizes distortion of the eye lens which causes less than optimal correction to patients' vision. The criss-cross channels prevent or minimize damage to the cornea, sclera and conjunctiva which has been a

documented problem in LASIK and other keratome procedures using apparatus such as relied upon by the Examiner. The criss-cross channels permit a low-profile device which can fit under patients' eye lids, obviating the need for a lid speculum, thereby reducing complications in patient recovery and reducing obstructions during surgery. These complications are especially relevant for patients with narrow ocular orbits. Dr. Will's Affidavit also provides citation to references which provide objective evidence to back up his explanations of the differences and advantages of his invention over the prior art demonstrating the unobviousness of the claims. *See Affidavit of Dr. Will* ¶¶ *7-8*.

Moreover, "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986). The Examiner's rejections amount to using that which Dr. Will teaches in his patent against him by selectively choosing elements of several references and combining them without explanation of objective evidence which would lead a person to combine the references - at which point the Examiner argues it would be obvious to further modify the combined elements of the various references to achieve the claimed invention by adding criss-cross vacuum channels, again without any suggestion, teaching or motivation or objective evidence. This is exactly the type of hindsight analysis that is so often rejected in court decisions.

Both Hellenkamp and L'Esperance teach vacuum rings with annular vaults requiring the use of lid specula causing greater discomfort for patients. *See Affidavit of Dr. Will at ¶ 8.* L'Esperance '172 (cited by Examiner), which is a continuation-in-part of Application 891,285 issued as L'Esperance '148 (also cited by Examiner), specifically teaches the requirement of using a lid speculum and can therefore be viewed as

teaching away from apparatus and methods which do not require such. *See L'Esperance '172, col.3, ll.50-59.* "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 45 USPQ2d 1977 (Fed. Cir. 1998). *See also* The Dow Chemical Co. v. U.S.,18 USPQ2d 1657 (Ct. Cl. 1990). The use of criss-crossed channels with alternating lands and grooves, a recited element in all claims of the present invention, eliminates the need for annular vaults thereby creating a lower profile device. This lower profile eliminates the need for a lid speculum in most cases, and is more comfortable for patients, especially those with narrow or tight lid openings. This fundamentally distinguishes the present claims from L'Esperance.

Examiner incorrectly states that there is no disclosure in the Application relating to holding the corneal surface flat, without displacement into the criss-cross vacuum channels. The original specification at page 6, lines 12-20, states:

> "When placed on the eye, with the contact portion **14** contacting directly upon the eye and encircling the cornea, the criss-crossing channels **16** are upon the eye globe conjunctiva. Vacuum port **18** communicates with channels **16** such that vacuum pressure exerted at the vacuum port **18** creates vacuum pressure in the criss-crossing channels **16**, *sucking the eye globe conjunctiva attached to the sclera flush against the contact portion **14***. This fixates the eye. The criss-crossing channels **16** work to oppose the suction created by each other, such that *the eye glove conjunctiva attached to the sclera, is spread taut between the channels **16**, instead of being sucked upon into a particular channel*."

Specification, page 6, lines 12-20 (emphasis added). Further, the Specification's "Summary of the Invention", at page 4, lines 11-21, recites decreased trauma to the ocular surface and the ability to more easily reposition the fixation device after vacuum has once been applied as specific advantages of the present invention. Further, Dr. Will's accompanying Affidavit for further evidence in this regard. In contrast, the

Hellenkamp reference relied on by the Examiner specifically acknowledges that the cornea is displaced into the hollow vacuum ring to contact the surface of the vacuum enhancer. *Hellenkamp at col.9, ll. 23-43.* Conversely, the Examiner provided no record evidence to support his incorrect factual assertion that the present invention does not draw the cornea surface to contact against the flat land between the criss-cross channels, rather than into the channels themselves, as claimed and described.

Additionally, the use of criss-cross channels (a recited element of each claim) avoids the problem of clogging which porous surfaces (such as taught in L'Esperance) are subject to. The use of channels also permits a lower profile than devices using a porous surface can achieve because there is no need for the vacuum annulus above the porous surface (as taught in L'Esperance). Thus, the present invention provides unobvious solutions to the problems inherent in existing apparatus and methods.

Examiner incorrectly stated that "with regard to Hellenkamp, applicant theorizes a problem with the reference, but does not associate it with any particular structure of the device." The Affidavit of Dr. Will directly addresses the inherent problems with existing devices and methods and the specific structures and methods which solve these problems. Applicant has made clear that a significant disadvantage of existing designs such as Hellenkamp, Curtin, and others is that they rely on a hollow annular ring to apply vacuum, which causes the cornea surface to displace into the vault of the ring. The vacuum enhancer taught by Hellenkamp reduces this problem in certain respects, but does not eliminate it. Applicant has also explained that the vault – inherent in the design of existing hollow annular rings, including Hellenkamp, Curtin and L'Esperance – creates the need for a lid speculum during procedures, which is generally eliminated by the low profile of the criss-cross channel design which is recited in all claims of the present invention. Applicant, by pointing out these specific drawbacks of existing apparatus and

methods, does not argue that these references are inoperative or invalid, but merely that they are not perfect solutions. The present invention represents a significant improvement over existing apparatus and methods in many respects, discussed in detail in Dr. Will's Affidavit. The Examiner incorrectly implies that by claiming improvement over the existing art Applicant must thereby prove the existing art lacks utility.

Examiner describes the pores of L'Esperance as lands and grooves but cites no support for this. *See June 14, 2007 OA at pp. 10-11.* A porous surface would necessarily be considered smooth, lacking lands and grooves. Referring to L'Esperance's porous surface as lands and grooves extrapolates the minimal teachings of L'Esperance much too far. L'Esperance teaches a porous, air-permeable membrane. This is not equivalent to criss-crossing channels creating lands and grooves. L'Esperance applies suction through a porous membrane via an annular chamber above the porous membrane. *See L'Esperance '127 at col.4, ll.26-34.* This is the only method taught by L'Esperance '127 and its related applications. *See e.g. L'Esperance, Jr. '148 (also cited by Examiner) and L'Esperance, U.S. 4,665,913, incorporated by reference into L'Esperance '148.*

Examiner is correct to note that the porous surface of L'Esperance distributes vacuum over its surface to improve stability. However, such porous surfaces are subject to clogging. All porous materials are subject to clogging, a simple fact of nature which Dr. Will has confirmed with real-world experience in performing thousands of eye surgeries. Examiner has cited nothing in L'Esperance or any other reference suggesting special properties which render L'Esperance's porous membrane not subject to clogging. Rather than placing the burden on Applicant to find a reference describing L'Esperance's shortcomings, the burden rests with Examiner to cite a reference explaining how Dr. Will's description of L'Esperance's tendency to clog is not correct.

The fact that L'Esperance does not address this problem does not render it inapplicable – L'Esperance was primarily focused on issues not related to the eye fixation methods. Hellenkamp, and Dr. Will's Affidavit, both address significant problems with buildup of mucous and other debris within vacuum channels leading to occlusion. Examiner fails to explain how the pores of L'Esperance are magically free of clogging issues whereas the full bore annular vacuum rings of Hellenkamp are subject to occlusion. Dr. Will stated in his affidavit that based on his actual experience conducting surgeries that the porous membrane of L'Esperance would be subject to clogging. *See Aff. Dr. Will at ¶ 9.*

Examiner at p.6 (*see June 14, 2007 OA*) states, "It is not clear to the examiner why" a low profile device obviates the need for a lid speculum. Respectfully, the Examiner's lack of expert knowledge is not a basis for rejection. Dr. Will's affidavit explains that devices relying on a vacuum annulus require use of a lid speculum. He has performed thousands of eye surgeries. If Examiner does not have a reference which contradicts Dr. Will's affidavit then it must be taken at face value. Respectfully, Applicant submits that if the Examiner disputes facts in Dr. Will's affidavit then the burden rests on Examiner to prove his contentions based on references which can be made part of the record, so that Applicant may respond and reviewing bodies can review the evidence. Moreover, regardless of whether Examiner was able to review the articles referenced by Dr. Will in his affidavit, Dr. Will has stated that based on his direct experience, that of his staff, and his research, existing devices operating similar to L'Esperance and Hellenkamp face limitations which the present invention addresses. Applicant submits that the Examiner failed to cite reliable references in the record.

Examiner at p.7 (*see June 14, 2007 OA*) states that L'Esperance's membrane forms only "a portion" of the device but extends beyond the annular chamber and so would fit under the eye lid. Applicant points out that this extending lip does not convey

vacuum as there is no vacuum source above it. A membrane would conduct vacuum only through its plane, not laterally. Thus the annular chamber necessarily is concurrent in area with the vacuum-affected surface of the membrane. The annular access provided for surgical access is inside the inner diameter of the vacuum annulus. By contrast, as pointed out in Dr. Will's affidavit and the specification, the criss-crossing channels extend fro the annulus provided for surgical access outward, with no vacuum annulus above them. The criss-cross channels therefore provide an inherently lower profile. Again, neither L'Esperance nor Applicant's figures are drawn to scale so Examiner's attempts to measure proportions is inappropriate. One can observe the structures and note that there is indeed, necessarily, a vacuum annulus extending vertically above the membrane of L'Esperance (see Fig. 1, #10, 11, 12 & col. col. 4 ll. 28-35), while the vacuum channels of claims 1, 11 and 12 extend laterally with no vertical vacuum annulus rising above, allowing a narrow profile for an eyelid to fit over (see Fig. 4).

Examiner at page 5 (*see June 14, 2007 OA*) equates the vacuum distributor inside the suction ring of Hellenkamp equates to the distributed lands and grooves created by the criss-crossing channels of claims 1, 11 and 12. *See June 14, 2007 OA.* The problem with Examiner's evaluation is that in Hellenkamp the sclera does not contact the surface of the insert *until it has been sucked into the annulus of the vacuum ring* – thus substantially all of the damage has already been done. Nowhere does Hellenkamp teach, nor do the drawings of Hellenkamp illustrate, a flush-mounted land and groove contact surface. Hellenkamp never contemplated a solution involving anything other than a vacuum ring. Moreover, Hellenkamp merely attempts to distribute vacuum more evenly – but this is only a partial solution. The real damage is caused by displacement into the vacuum ring itself, which Hellenkamp does not prevent.

L'Esperance, while able to prevent displacement has the potential of causing the opposite problem. If the pores of L'Esperence clog then either of two outcomes is likely. Either vacuum hold will be lost, allowing the fixation apparatus to move or separate completely from the cornea, or, the clogged pores will lock the vacuum between the membrane surface and the conjunctiva with no way to break the vacuum. The result is that the apparatus must be separated under vacuum potentially tearing the sclera. Either outcome is undesirable. The criss-cross channels of Applicant's invention prevent displacement into a annular vacuum ring without the danger of clogging created by L'Esperance's membrane.

The lands of the criss-crossing channels provide the contact surface without being drawn into an annular ring. The vacuum channels are on opposing sides of any given land such that they act against one another to pull the sclera against the lands between rather than displacing into the channels themselves.

B. <u>Claims 2 and 13</u>

Dependent Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin. Traversal with respect to L'Esperance or Hellenkamp is reasserted regarding independent claims 1, 11 and 12 and further with regard to their combination with Curtin, which teaches a conventional hollow annular ring. *Curtin, col.5, ll. 46-51.*

The Examiner asserts that "Curtin teaches the use of adjustment arms on eye fixation devices." *OA July 14, 2006, at p.5.* Applicant respectfully disagrees. Curtin specifically teaches that the rigid vacuum tube 128 holds annular ring 124 stationary over an eyeball, at which point the patient is provided a target to focus on which aligns the eye to the apparatus. Vacuum is applied to annular ring 124 which then "locks the ring arrangement 122 on the patient's eye when the patient's visual axis is aligned with

the target." *Curtin, col.6, ll. 1-8; col. 7, ll. 29-39 & 63-68.* Curtin does not, alone nor in combination with other references cited, teach or suggest the use of adjustment arms connected to an eye fixation apparatus which permit adjustment of the apparatus to the eyeball prior to fixation, rather than having the eyeball align itself to a vacuum ring. Thus Curtin teaches exactly the opposite methodology of the current invention recited in claims 2, 13 and 22, which renders it less optimal than the current invention.

Dr. Will, in his affidavit, notes several advantages from the use of adjustment arms. *See Affidavit of Dr. Will ¶ 10.c.* Maneuvering the device is easier, and there is less chance that inadvertent contact will scratch the conjunctival surface or cause contamination. While the single adjustment arm of Curtin may have 3-D adjustment capability as argued by Examiner, such capability does not equate to the ease of use provided by the arms of the present invention which would allow a surgeon to grip the arms with each hand while sighting through the annular access hole with a sighting device, rather than the cumbersome apparatus described in Curtin. A person of skill in the art would not see the combination of Curtin with L'Esperance and/or Hellenkamp as teaching the combination of elements of claims 2 and 13.

C. <u>Claims 3, 4, 7, 8, 14, 15, 18 and 19</u>

Dependent Claims 3, 4, 7, 8, 14, 15, 18 and 19 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin and/or Clark et al, and further with respect to Ruiz. (The Examiner had previously cited Ruiz, *see April 11, 2006 OA*, but while not repeating the rejection with Ruiz did not explicitly withdraw it either.)

Examiner incorrectly states that "Clark et al teach employing X- and Y- axis adjustment mechanisms on eye fixation devices." *See June 14, 2007 OA at p.15.* Applicant respectfully disagrees. Applicant has not claimed the concept of X-Y

adjustment, but a particular apparatus and method of lateral and cross-lateral position adjustment integrated into an eye fixation apparatus for use during surgical procedures. Clark is not directed to the *positioning* of surgical devices *during surgery*. The adjustment taught by Clark relates to adjusting the platform of a microscope set upon a stable base, away from any surgical procedure, so as to permit the proper depth setting of a microkeratome blade to be used in surgery. Clark, even in combination with L'Esperance and Hellenkamp, does not teach or suggest the elements of translation guide members adjustably connected to an eye fixation apparatus during surgery, nor the additional elements of translation rods with adjustment knobs to provide fine control.

Examiner's additional reliance on Ruiz does not disclose the elements of the claim either. Ruiz teaches a geared cutting blade on a base which lacks the ability to fix the eye in space, and so still fails to disclose, even in combination, all of the elements of the rejected claims. Ruiz does not disclose a translation member "adjustably connected" to an eye fixation apparatus. The blade guide of Ruiz allows for movement but not adjustment. Ruiz does not teach the use of a threaded guide rod and adjustment knob for adjusting position. Nor does Ruiz teach the use of a second translation guide member non-parallel to a first translation guide member to permit X-Y adjustments.

Reference to Ruiz, Figure 10, also demonstrates the type of lens distortion created by existing apparatus and methods which the present invention is specifically designed to avoid. The Examiner has not established a prima facie case of obviousness under Section 103(a).

As Dr. Will's Affidavit makes clear, the ability to adjust the fixation apparatus to the eyeball, rather than vice versa, provides for better adjustment and concentration properties during laser procedures. This adjustment capability is enhanced by the addition of lateral translation members directly to the eye fixation apparatus. Translation

guide rods with knob adjusters allow precise adjustments while requiring less manual dexterity than current apparatus and methods. The translation guide rods also prevent further distortion of the eyeball caused by forcing the eyeball into alignment with the surgical apparatus.

Applicant understands and appreciates Examiner's explanation of how adjustment screws operate, but this does not render the claims obvious. (Nor does Examiner's discussion render the claims invalid as lacking enablement, which seems to be implied by the Examiner.) The statement Examiner refers to is at paragraph 11 of Dr. Will's affidavit, where he refers to the fact that seemingly minor changes in apparatus and methods can actually achieve significant results in surgical procedures where "adjustments in the sub-micron range" can alter outcomes. The reference was to all of the differences over the prior art in the previous ten paragraphs. Thus, the reductions in eye deformity, intraocular pressure variations, reductions in hydration variation of the cornea, improved positioning capabilities, improved re-positioning capabilities, improved adjustment capabilities, and lessened complications achieved by the apparatus and methods claimed, all lead to significantly improved outcomes individually and cumulatively. The point was that improvements over prior art devices in positioning or focusing LASIK apparatus may, in some cases, only be in the sub-micron range, but even such small *improvements* can be significant.

In addition, Dr. Will's affidavit makes clear the differences between the present invention and the asserted references. X-Y adjustment ability and the use of docking screws for setting and adjusting surgical apparatus prevents further distortion of the eyeball caused by forcing the eyeball to alignment with the apparatus, rather than vice versa. It also eliminates the need for expensive and complicated software to adjust for laser offset. The claims are unobvious.

D. **Claims 5, 6, 9, 10, 16, 17, 18 and 19**

Dependent Claims 5, 6, 9, 10, 16, 17, 18 and 19 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp and Curtin in combination with Clark et al, and further in regard to Ruiz and/or to U.S. 6,613,061 Olson. Applicant does not claim to have invented docking screws, but the claims as a whole incorporating docking screws are novel and unobvious. None of the cited references, even in combination, teach all the elements of the rejected claims. The dependent claims listed incorporate all of the elements of the claims from which they depend.

The cited references simply do not disclose the elements of the present invention. Applicant reiterates the discussion above, relating to the lack of teaching of first and second translation guide members in the cited references. The references, even in combination, do not teach employing x- and y-axis adjustment mechanisms movably connected to eye fixation devices during surgery, as discussed above. Clark et al does not teach the use of docking screws to tighten against objects inserted into the cylindrical space formed by the first (or second) annular translation guide members. Clark teaches only bench alignment of cutting devices, which devices are then used in ophthalmic surgery. Examiner's additional reliance on Ruiz does not disclose the elements of the claim either. Ruiz teaches a geared cutting blade on a base which lacks the ability to fix the eye in space, and so still fails to disclose, even in combination, all of the elements of the rejected claims. Ruiz does not disclose use of docking screws to tighten against objects in the annulus, especially considering Ruiz teaches a movable cutting blade. Nor does Ruiz teach the use of a second translation guide member non-parallel to a first translation guide member to permit X-Y adjustments with a docking screw. The Examiner has not established a prima facie case of obviousness under Section 103(a).

The references, even in combination, teach the use of docking screws to dock surgical devices to translation guide members at all, much less translation guide members which are adjustably connected to an eye fixation apparatus during surgery. The addition of docking screws to dock surgical apparatus, such as lasers or optical cones, directly to the eye fixation apparatus ensures even more precise alignment to achieve superior concentration properties in laser procedures. *See Affidavit of Dr. Will.*

E. Claim 22

Independent Claim 22 stands on its own. Examiner rejected claim 22 under § 103(a) based on a combination of L'Esperance or Hellenkamp in combination with Curtin and Clark et al, and further in combination with Olson. Claim 22 includes all of the elements of claims 1-10 but explicitly recites the limitation "wherein the eye fixation portion has a low profile convex bottom contact portion..." and "...is substantially narrow so as to fit under the eye lid of a patient without the use of a lid speculum." Support for claim 22 is found in the Specification at page 4, ll. 11-14 and Fig. 4. The Specification, at page 4, lines 11-14, describes a feature of the invention that "(1) functions without the need for a lid speculum; (a) low profile fits comfortably under the lids; (b) can more easily be used on patients with "tight lids" which are common to some races..."

Applicant reasserts each of the arguments regarding rejections of claims 1-21, above, in regard to Claim 22. None of the cited references, even in combination, discloses all of the elements of claim 22 much less discloses the combination of the elements. Specifically, none of the references discloses a low profile fixation portion with criss-cross channels, first and second translation guide members with adjustment rods and knobs, docking screws in the first and second translation guide members, wherein the profile of the fixation portion – i.e. the structure containing the vacuum channels – is low enough to fit under the eye lid of a patient to obviate the need for a lid

speculum.

F. Method Claims 11-21.

Applicant asserts that method claims 11-21 stand on their own. Examiner has cited no reference or combination of references which recite the steps of method claims 11-21, but has merely cited references which include some, but not all, structural elements of apparatus claims 1-10. Applicant here reasserts all of the arguments relating to apparatus claims 1-10 relating to structural limitations inherent in claims 11-21, and additionally argues that the method steps are not disclosed by any combination of references, nor are they disclosed by any obvious modification of such references. Therefore, even if apparatus claims 1-10 and 22 are held obvious, Applicant submits method claims 11-21 are not thereby rendered obvious and stand on their own.

SUMMARY

For the foregoing reasons, Appellant believes that the Examiner's rejections of Claims 1-22 were erroneous, and reversal of the decisions is respectfully requested.

Respectfully submitted,

RYLANDER & ASSOCIATES PC

KURT M. RYLANDER
USPTO Reg. No. 43,897
406 West 12th Street
Vancouver, Washington 98660
(360) 750-9931

CLAIMS APPENDIX

1. (Original) An eye fixation apparatus, comprising:

an eye fixation portion, wherein the eye fixation portion has an annular convex bottom contact portion, which goes upon the surface of an eyeball and encircles the cornea, and wherein the contact portion is provided with criss-crossing channels; and

a vacuum port connected to said eye fixation portion and in communication with said criss-crossing channels such that vacuum pressure applied to said vacuum port exerts vacuum pressure through such criss-crossing channels to pull the eyeball membrane to the criss-crossing channels.

2. (Original) The eye fixation apparatus of claim 1, further comprising adjustment arms connected to said eye fixation portion.

3. (Original) An eye fixation apparatus of claims 1 or 2, further comprising a first annular translation guide member adjustably connected to the eye fixation portion, wherein the first translation guide member portion can translate laterally in relation to the eye fixation portion.

4. (Original) The apparatus of claims 3, wherein the first translation guide member is provided with a first translation rod and a first adjustment knob for translating the first translation guide member.

5. (Original) The apparatus of claims 3, further comprising a docking screw screwed through the first translation guide member for tightening the first translation guide member against objects inserted into the cylindrical space formed by the first annular translation guide member.

6. (Original) The apparatus of claims 4, further comprising a docking screw screwed through the first translation guide member for tightening the first translation guide

member against objects inserted into the cylindrical space formed by the first annular translation guide member.

7. (Original) The apparatus of claims 4, further comprising a second translation guide member adjustably connected to the first translation guide member, wherein the second translation guide member can translate laterally in relation to the first translation guide member in a direction not parallel to the translation of the first translation guide member.

8. (Original) The apparatus of claims 7, wherein the second translation guide member is provided with a second translation rod and an adjustment knob for adjusting the second translation guide member.

9. (Original) The apparatus of claims 7, further comprising a docking screw screwed through the second translation guide member for tightening the second translation guide member against objects inserted into the cylindrical space formed by the annular second translation guide member.

10. (Original) The apparatus of claims 8, further comprising a docking screw screwed through the second translation guide member for tightening the second translation guide member against objects inserted into the cylindrical space formed by the annular second translation guide member.

11. (Original) A method of fixating an eye cornea for surgery, comprising:

placing an eye fixation apparatus upon the eye globe conjunctiva around the cornea, wherein the eye fixation apparatus comprises an eye fixation portion with an annular convex bottom contact portion provided with criss-crossing channels, and a vacuum port connected to said eye fixation portion and in communication with said criss-crossing channels such that vacuum pressure applied to said vacuum port exerts vacuum pressure through such criss-crossing

channels to pull the eyeball membrane to the criss-crossing channels; and

applying vacuum pressure to said vacuum port creating a pressure differential through said criss-crossing channels in relation to said conjunctiva, adhering said conjunctiva to said contact portion.

12. (Original) The method of claims 11, further comprising:

checking to see said eye fixation apparatus is centered around the cornea; and

shutting off the vacuum pressure if said eye fixation apparatus is not centered around the cornea, recentering said eye fixation apparatus, and reapplying said vacuum pressure.

13. (Original) The method of claims 11 or 12, wherein the eye fixation apparatus is further provided with adjustment arms connected to said eye fixation portion.

14. (Previously Presented) The method of claims 11 or 12, further comprising adjustably connecting a first annular translation guide member to the eye fixation portion to translate said first guide member laterally in relation to the eye fixation portion.

15. (Previously Presented) The method of claim 14, wherein the first translation guide member is adjusted using a first translation rod and a first adjustment knob.

16. (Previously Presented) The method of claim 13, further comprising tightening the first translation guide member against objects inserted into the cylindrical space formed by the first annular translation guide member with a docking screw threaded through the first translation guide member.

17. (Previously Presented) The method of claim 14, further comprising tightening the first translation guide member against objects inserted into the cylindrical space formed by the first annular translation guide member with a docking screw threaded through the first translation guide member.

18. (Previously Presented) The method of claim 14, further comprising adjustably connecting a second translation guide member to the first translation guide member to translate said second guide member in a direction non-parallel to the first guide member.

19. (Previously Presented) The method of claim 18, wherein the second translation guide member is adjusted using a second translation rod and a second adjustment knob.

20. (Previously Presented) The method of claim 18, further comprising tightening the second translation guide member against objects inserted into the cylindrical space formed by the second annular translation guide member with a docking screw threaded through the second translation guide member.

21. (Previously Presented) The method of claim 19, further comprising tightening the second translation guide member against objects inserted into the cylindrical space formed by the second annular translation guide member with a docking screw threaded through the second translation guide member.

22. (Previously Presented) An eye fixation apparatus, comprising:

an eye fixation portion, wherein the eye fixation portion has a low-profile annular convex bottom contact portion, which goes upon the surface of an eyeball and encircles the cornea, and wherein the contact portion is provided with criss-crossing channels;

a vacuum port connected to said eye fixation portion and in fluid communication with said criss-crossing channels;

a first annular translation guide member with a first translation rod and first adjustment knob, adjustably connected to the eye fixation portion, wherein the first translation guide member portion can translate laterally in relation to the eye fixation portion using said first adjustment knob acting upon said first translation rod;

a second annular translation guide member with a second translation rod and second adjustment knob, adjustably connected to the first translation guide member, wherein the second translation guide member portion can translate laterally in relation to the first translation guide member and eye fixation portion using said second adjustment knob acting upon second first translation rod;

a first and a second docking screw screwed through said first and second translation guide members, respectively, and for tightening the first and second translation guide members against objects inserted into the cylindrical space formed by the first and second annular translation guide members; and

wherein, the profile of said eye fixation portion is substantially narrow so as to fit under the eye lid of a patient without use of a lid speculum.

EVIDENCE APPENDIX

An Affidavit under Rule 1.132 Traversing Rejections of claims 1-22 was filed on January 12, 2007, by Applicant Dr. Brian R. Will, as part of the RCE filed on the same date. The Examiner admitted the Affidavit by reference in the Office Action dated April 11, 2007 at pages 2-10.

A peer reviewed journal article referenced in the Affidavit of Dr. Will, *supra*, is submitted herewith: Julie M. Albietz, Lee M. Lenton, Suzanne G. McLennan, *Dry Eye After LASIK: Comparison of Outcomes for Asian and Caucasion Eyes*, JOURNAL OF CLINICAL AND EXPERIMENTAL OPTOMETRY 88:2 (2005), at pp. 89-96. The Examiner admitted the evidence by reference to the abstract in the Office Action dated April 11, 2007, at page 7.

The abstract of a peer reviewed journal article referenced in the Affidavit of Dr. Will, *supra*, is submitted herewith (the Applicant was unable to obtain a printed copy of the entire journal article in time for submission): Sun L, Liu G, Ren Y, Li J, Hao J, Liu X, Zhang Y., *Efficacy and Safety of LASIK in 10,052 eyes of 5,081 Myopic Chinese Patients*, JOURNAL OF REFRACTIVE SURGERY, vol. 21 (5th Supplement), at S633-5 (Sept-Oct 1995).

Enclosed:

(1) Affidavit of Dr. Brian R. Will under Rule 1.132 Traversing Rejections dated January 12, 2007 (19 pages).

(2) Julie M. Albietz, Lee M. Lenton, Suzanne G. McLennan, *Dry Eye After LASIK: Comparison of Outcomes for Asian and Caucasion Eyes*, JOURNAL OF CLINICAL AND EXPERIMENTAL OPTOMETRY 88:2 (2005), at pp. 89-96 (7 pages).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: BRIAN R. WILL

Serial No.	10/608,408	Examiner:	Shay, David M.
Filed:	June 27, 2003	Group Art Unit:	3735

For: EYE FIXATION APPARATUS

Date: January 10, 2007

Mail Stop RCE
The Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT UNDER RULE 1.132 TRAVERSING REJECTIONS

I, BRIAN R. WILL, hereby declare under penalty of perjury based on personal first hand knowledge the following to be true and accurate:

1. I write this declaration to overcome and traverse rejections made under Section 103 in the July 14, 2006 Final Office Action. This declaration is submitted in conjunction with a Request for Continued Examination.

2. I am a board certified Ophthalmologist with over 17 years of practice. I have performed over 28,000 LASIK procedures as well as over 10,000 other ocular procedures in that time, and currently perform over 3,000 LASIK procedures per year. I have intimate experience with much of what has been considered state of the art in the field of LASIK and other keratome procedures, using lasers and microkeratome blades, including the devices incorporating the Hellenkamp (U.S. 6,042,594), Clark (U.S. 5,591,174), Curtin

(U.S. 4,173,980) and L'Esperance (E.P. 0372127A1) references, or similar to these references, cited by the Examiner. This declaration is made based on my personal experience and that of my staff of two (2) ophthalmologists within the field.

3. My invention provides an improved apparatus and method for fixing the eye during keratome surgeries, and for adjusting surgical devices to the fixated eyeball during procedures. The improvements relate both to the improved accuracy of the surgery due to reduced distortion of the eyeball and greater precision of positioning, as well as reduced damage to the cornea, sclera and conjunctiva. These improvements are concrete. The improvement in outcomes includes: greater measured improvements in visual acuity for patients; less discomfort for patients during and after surgery; less damage to the cornea, sclera and conjunctiva during surgery; less discomfort for patients with narrow lid openings; and allows patients that have small lid fissures / apertures to undergo LASIK whereas existing technology denies them such an opportunity.

4. Regarding independent claims 1 and 11, a fundamental reason for the improved performance of the apparatus is the criss-cross channel design of the vacuum ring. The criss-cross channel design provides several specific benefits over existing devices:

a. The lands between the channels provide multiple contact points spread over a wider surface, preventing the cornea, sclera and conjunctiva from being displaced into the vacuum channels and providing a more stable contact, preventing "rocking" on the eye.

b. The use of criss-cross channels prevent occlusion of the vacuum source which can lead to loss of vacuum – and loss of eye fixation – during surgical procedures.

c. The use of criss-cross channels markedly reduces deformation of the eye and reduces intraocular pressure – thus it is safer, more comfortable, and provides improved accuracy, especially in Femtosecond procedures.

d. The use of criss-cross channels to distribute vacuum, rather than a vacuum annulus, creates a lower profile device thereby obviating the need to use a lid speculum, and providing more clearance in a tight space during procedures.

e. The surgeon is able to reposition the fixation device if the initial positioning is incorrect, because the criss-cross channels do not cause gross distortion of the cornea, sclera and conjunctiva, whereas existing devices prevent repositioning due to the indentation and elevation of a ring of tissue on the cornea, sclera and conjunctiva when conventional fixation devices are removed.

f. The use of shallow criss-cross channels allows for more rapid and thorough cleaning of the apparatus, providing quicker turnaround time between patients and extending the life of the devices themselves.

g. The addition of X-Y translation guides, see dependent claims 3-10 and 14-21, provide adjustment capabilities built in to the fixation device which allow for superior centration properties in laser procedures.

h. The addition of docking screws, see dependent claims 5, 6, 9, 10, 16, 17, 19, 20 and 21, for docking surgical devices into the fixation aperture, rather than conventional pincer type docking systems, provide smoother docking with less manual dexterity required.

5. The criss-cross channel design, claims 1 and 11, allows a lower vacuum setting to achieve the same fixation of the eye, and the narrowness and cross-orientation prevent significant displacement of the cornea, sclera and conjunctival tissue into the vacuum channels. Existing annular vacuum rings, such as taught by the Hellenkamp and Curtin references cited by Examiner, displace significant amounts of tissue into the vacuum ring cavity, leading to several drawbacks.

a. First, by drawing the ocular tissue into the annulus it can (and often does) damage the ocular tissue. Often this damage does not create problems, but under certain circumstances it can. In one example, if the initial setting of the fixation device is incorrect then the displacement can prevent repositioning because it leaves an indentation and a swollen ridge conforming to the annulus. The annular ring creates a ridge (rather like a "hickey") on the cornea, sclera and conjunctiva – the displaced ring of ocular tissue remains that way for some time. A second attempt at surgery can only be made after this annulus-shaped "hickey" has healed

because it prevents proper re-alignment of the vacuum ring itself. A second example of the problem created is when the displacement causes separation of the conjunctiva from the underlying scleral tissue – a condition called "chemosis." Some patients are more susceptible than others, but with the growth of LASIK and other surgical procedures this is becoming a more and more significant problem. Since the majority of inflammatory tissue in the eye is located in the conjunctiva, trauma to that tissue in the form of chemosis or, trauma in general, can significantly increase the amount of inflammation in the eye following surgery, which can lead to serious inflammatory complications such as Diffuse Lamellar Keratitis, that can markedly alter healing and the surgical result. A third example of problems resulting from conjunctival displacement is that, even without a complete separation such as in chemosis, the damage caused by conjunctival displacement can lead to subconjunctival hemorrhaging, which appears as a red blood spot on the eye. Although not generally dangerous, it is undesirable for the patient (and a poor advertisement for surgeons).

b. The apparatus and method described in claims 1 and 11 reduce these risks in several ways. First, the criss-cross channels are shallow and distributed over a wide area which conforms to the shape of the eyeball, because they are surface grooves rather than an annulus. Second, the separate channels pull the corneal, conjunctival and scleral surface taught between them and provide many lands, conforming to the

natural shape of the eyeball, for contact area. In other words, rather than being drawn into the channels the corneal tissue is held against the lands, resulting in minimal displacement. Third, because the channels are spread over a wide area rather than a narrow ring a lower vacuum pressure can be used to achieve the same stability. The ability to hold the eyeball in place is determined by both the vacuum pressure multiplied by the total area of the channels or annulus (i.e. the absolute force applied), as well as the depth over which the force is distributed (i.e. the wider the base of application, the more stable the support provided by the fixation apparatus – proportional to the moment of inertia). Therefore, multiple points of contact spread over a wider band create a more stable base than narrower annular vacuum rings, or conversely, lesser vacuum pressure is required to achieve comparable stability – which in turn reduces the likelihood of all the complications associated with vacuum fixation devices. For example, the apparatus and method of claims 1 and 11 requires lower vacuum levels than for conventional annular devices, using the system described in Hellenkamp, that I have significant experience with. Although the L'Esperance reference, cited by Examiner, is an improvement over annular designs in this last regard, the porous membrane of L'Esperance is subject to clogging (see ¶ 9, below), and the annular vault necessitates a lid speculum (see ¶¶ 7-8, below).

c. A second advantage of the apparatus and methods of claims 1 and 11 is that they avoid the excessive deformation of the

eyeball, and consequently the cornea, during a LASIK or other keratome procedure, which is caused by annular vacuum rings. This deformation leads to dual problems of less accurate correction due to the distorted cornea, and raised pressure within the eye which can lead to more dangerous complications such as occlusion of the blood supply. The high vacuum and eyeball distortion caused by annular rings frequently result in the cornea being compressed so that it is thinner than normal and it also assumes a completely abnormal shape and contour. Although the eye is somewhat elastic, it does not immediately rebound to its natural shape or thickness after the vacuum or vacuum ring is released. The eyeball distortion and occlusion of the arterial blood supply also renders the iris to be temporarily ischemic, thereby temporarily altering its shape and the normal pupil response time to light and accommodation. These distortions of normal eye conditions are important factors in less than optimal surgical outcomes.

d. In addition, this distortion and compression alters the normal water content of the cornea from its natural state. The accuracy of the LASIK procedure depends on three primary factors: accurate cutting of the keratome flap, accurate placement and control of the Femtosecond and excimer lasers, and the shape and condition of the cornea when it is lazed. Excimer lasers used to photoablate corneal tissue assume a normal state of corneal hydration as well as a predictable corneal contour and shape. Individual variations in the water content of the cornea caused

by corneal compression from the annular vacuum ring cannot be predicted or accounted for by the excimer lazing processes. In addition, most excimer lasers require that the ablation profile be modified on an individual basis to account for the angle of incidence of the excimer beam at the exact point of beam application on the curved corneal surface. Because the annular vacuum ring deforms the eye and the tissue is not immediately elastic following ring removal, the exact shape of the contour to the cornea is no longer known and attempts to precisely compensate for angle of incidence effects on excimer beam efficiency based upon preoperative corneal shape measurements are no longer accurate or valid.

e. Compression of the corneal tissue, caused by annular vacuum rings, also creates errors in creating a predictable flap thickness, as current Femtosecond and keratome devices determine flap depth by measuring from the anterior surface of the cornea only. Tissue compression of the anterior corneal tissue or the entire cornea of only a few microns will cause such a device to create a flap that is significantly thicker than expected. Excessively thick or unpredictable flap thickness is one of the leading sources of error in LASIK surgery and predisposes the subject eye to structural weakness and risk for ectasia. Eye tracking excimer lasers frequently use the iris and pupil as a landmark for reference for the tracking apparatus so as to compensate for intraocular eye movement and as a point reference for the centration of wavefront or topographically guided photoablation procedures. Subjecting the iris to

transient ischemia by high intraocular pressure from annular vacuum rings intraoperatively distorts the pupil and renders the iris less responsive to light and accommodation for a temporary period. These factors measurably reduce the accuracy of centration and thereby adversely effect the accuracy of the refractive treatment.

f. Therefore, based on these various factors: (1) preoperative measurements of corneal thickness, hydration state and contour are not accurate after the eyeball has been grossly deformed by high vacuum pressures; (2) flap thickness based on depth measurements from the anterior surface of the cornea after the tissue is compressed and distorted can no longer accurately predict flap thickness postoperatively; (3) distortion and distention of the iris and pupil due to transient iris ischemia introduces significant error in centration of the intended photoablative procedure as the pupil centroid is displaced from the normal preoperative position; and, (4) the excimer laser can no longer accurately compensate for tissue shape or tissue hydration consistency during the procedure as these factors have been modified intraoperatively by high vacuum. All of these factors create the propensity towards unpredictability of refractive endpoint and cause over and under corrections of the refractive error. Fixation devices such as Hellenkamp and Curtin cause unnecessary deformation: after sucking the sclera up into the vacuum chamber the targeting device flattens the cornea down, compressing the tissue and thereby introducing deformation error.

g. Hellenkamp specifically teaches that the annular-style vacuum ring "cause[s] the cornea to be urged upwardly and to protrude through the aperture 25 of the positioning segment 20..." *See Hellenkamp, col. 7, ll. 30-32.* Claims 1 and 11 significantly reduce the distortion due to the distributed vacuum channels. Lower vacuum is required to begin with since the channels are interspersed between surfaces which approximate the eye's natural shape, so the tissue is held against these lands. Minimal displacement of the cornea into the vacuum channels reduces the distortion of and pressure within the eyeball. And, the use of channels rather than a porous surface prevents clogging which can cause some areas to be held more tightly than other areas – leading to still more distortion as well as other potential complications (discussed below).

h. A third advantage of the apparatus and method of claims 1 and 11 is that the criss-cross channels are less susceptible to occlusion from displacement of the conjunctiva, sclera or cornea into the annulus and from mucus. Partial occlusion can result in some areas being held more tightly than others making those more tightly held areas more susceptible to chemosis or other trauma. Occlusion may also result in loss of vacuum during the surgical procedure with potentially devastating consequences. The Hellenkamp reference, cited by Examiner, specifically discusses some problems caused by displacing the sclera into annular rings, and attempts to solve these problems. The vacuum enhancer of

Hellenkamp is a partial solution to the problem of occlusion, making loss of vacuum less likely, but does not address the other drawbacks of annular designs discussed above. The sclera is still exposed to a continuous hollow annular chamber thereby causing a raised ring on the tissue. The hollow annulus also imposes a high profile, similar to L'Esperance, requiring a lid speculum and attendant disadvantages discussed above at paragraphs 7-8, below. Hellenkamp's solution is limited by the fact that it relies on modifying a conventional annular vacuum ring structure. Hellenkamp, at col. 3, ll. 20-44, discusses displacement of the conjunctiva into an annular chamber and problems of conjunctival separation and damage. Hellenkamp, at col. 3, ll. 20-44, discusses problems of vacuum chamber occlusion caused by displacement of the conjunctiva into the vacuum ring chamber. Hellenkamp, at col. 3, ll.45-61, discusses problems of mucus buildup in annulus-type rings and difficulty in cleaning due to the hardening of residual mucus debris. If buildup and hardening of mucus within an open channel is problematic, as taught by Hellenkamp in 1998, due to the inability to clean out the annulus chamber, then buildup and hardening of mucus is even worse in a porous surface such as taught by L'Esperance in 1988. Residual mucous material embedded in this porous material may introduce unwanted complications from cross contamination between patients, even despite sterilization procedures. Proteins, other biological macromolecules and debris transferred between patients from this porous

membrane that contacts sensitive eye tissue will increase postoperative inflammation and potential infection from viral, bacterial or prion residues. There is simply no effective way to clean the pores taught by L'Esperance so, in a relatively short time, the device will become unusable and require replacement. The apparatus and method of claims 1 and 11 reduce the likelihood of occlusion – through the use of cross-connected vacuum channels – and significantly reduce the other negative effects inherent to annular designs, as discussed above. The criss-cross channels are less subject to blockage because if one channel becomes blocked – for whatever reason – an alternate vacuum path remains. The criss-cross channels are significantly easier to maintain and clean because they are flat and shallow, rather than the vaulted annulus of existing devices.

i. Applicant does not argue that Hellenkamp, L'Esperance or any other reference cited, is non-functioning or invalid. Rather, Applicant through claims 1 and 11 provides unobvious solutions to verified real world problems.

6. The Examiner's Office Action of July 14, 2006, at page 2, states that since the L'Esperance patent states that it only claims to operate "solely upon the optically used area of the anterior surface of the cornea" (Examiner quoting the L'Esperance reference) then damage to the cornea due to the fixation device would "constitute operating on a portion of the eye which was other than the optically used portion of the cornea." I am an ophthalmologist and the Examiner's statement is incorrect – complications from surgery are not

"operating", they are complications. The recognition that a surgical procedure has side effects caused by the surgical devices does not render the side effects – unwanted and unintended – "operating." The Examiner's statement is even more perplexing considering the fact that the Hellenkamp reference, cited by Examiner, discusses some of the problems of corneal damage caused by annular vacuum rings at length. Hellenkamp attempted one method of solution, which turns out to be inadequate in certain critical respects. The goal of my invention, described in claims 1 and 11, which is actually achieved, is to reduce unwanted side effects and complications from surgery, and provide greater accuracy during surgery.

7. The criss-cross channels of my claims 1 and 11 reduce the potential for trauma to the cornea, a leading cause of post-LASIK complications. The incidence of subconjunctival hemorrhage has been estimated as high as 10% or more in LASIK patients. Thus, the problems associated with existing eye fixation apparatus are far from "speculative," as asserted by the Examiner, who provided no references to back up his incorrect assertions of fact. *See, e.g.,* Sun L, Liu G, Ren Y, Li J, Hao J, Liu X, Zhang Y., EFFICACY AND SAFETY OF LASIK IN 10,052 EYES OF 5081 MYOPIC CHINESE PATIENTS. *Journal of Refractive Surgery,* 2005 Sep-Oct; 21(5 Suppl):S633-5. PMID 16212294.

8. The low profile achieved by the criss-cross channel design eliminates the need for a lid speculum in most cases, including patients with narrow ocular fissures and orbits. Higher rates of complications from using annular fixation devices on patients with narrow ocular fissures and orbits, such

as patients of Asian descent, have been documented in medical studies. In at least one peer-reviewed study approximately 28% of Asian LASIK patients experienced prolonged or permanent "dry eye" following LASIK procedures. *See, e.g.*, Albietz JM, Lenton LM, McLennan SG., DRY EYE AFTER LASIK: COMPARISON OF OUTCOMES FOR ASIAN AND CAUCASIAN EYES, *Clinical and Experimental Optometry* 2005 Mar; 88(2):89-96. The study concluded that this was likely due, in part, to damage from the vacuum fixation apparatus caused by the tight fit of the suction ring and keratome device within their narrower orbits. Id, p.95. The criss-cross channels obviate much of this risk. The criss-cross channel design imposes fewer stresses on the cornea and eyeball to begin with. This design also allows use of a low profile, conforming, base which fits under the eyelid, rather than an annular vault, obviating the need for a lid speculum, which is required when using apparatus taught by Hellencamp, L'Esperance, and Curtin. Even in the absence of dry eye complications, lid specula carry the disadvantages of causing greater discomfort to the patient both during and after surgery, and creating space interference for the surgical team in an already tight working space.

9. I have reviewed the L'Esperance references cited by the Examiner, including the newly cited references (US 4,732,148 and US 4,770,172). All the L'Esperance references specifically claim annular vacuum designs applying suction through a permeable (i.e. porous) membrane, and thus all share the drawbacks of the high profile and difficult cleaning requirements of other annulus apparatus. Based on my experience the pores of the L'Esperance design are

quite vulnerable to clogging – as is the case with any porous membrane applied to mucus surfaces. I have found, based on extensive experience in thousands of surgical procedures, that devices such as that taught by L'Esperance have at least two major drawbacks that are not mere "speculation."

a. First, L'Esperance relies on applying suction through a porous surface backed by an annular chamber. The porous surface is subject to clogging by mucus from the conjunctiva surface – all porous surfaces are subject to clogging. This clogging in turn leads to the dual problems of causing blockage of the vacuum path and inadequate cleaning which shortens useful life. Mucus is difficult or impossible to clean out of porous surfaces, especially so after hardening, so the porous membrane device taught by L'Esperance would either have a very short useful life or it would require special cleaning procedures which would make surgical procedures significantly less economical. It is also anticipated that cross contamination from residual mucous material, bacteria and other biological macromolecules in the porous material would introduce significant risk to patients from infection and excessive postoperative inflammation from the transference of foreign biological molecules and material between patients. The Hellenkamp reference discusses the difficult problem of cleaning mucus and attempts to solve the problem by making part of his device disposable – a less than optimum solution. In addition to the danger of loss of vacuum, or uneven vacuum, if the pores become completely clogged during a procedure (due

to inadequate cleaning or other factors) the membrane will adhere to the corneal surface through surface tension of the mucus and water, which could easily cause damage when removed. (As an example, place a wet glass on a smooth surface or coaster – when it is lifted the coaster will adhere to the bottom of the glass.) This kind of force applied to the corneal surface – a delicate structure – can and will cause damage. This danger is especially pronounced in patients who are susceptible to chemosis or have abnormally poor adhesion of the epithelial layer such as a Basement Membrane Dystrophy, which is a very commonly occurring anomaly.

b. A second drawback of the L'Esperance reference, shared by other references cited by the Examiner, is the high profile of the vacuum chamber vault necessitated by annular designs. The high profile requires use of a lid speculum during procedures in order to hold the eyelids back. In a patient with narrow lid fissures, a high-profile vacuum ring such as L'Esperance may not be able to be used at all, with or without a lid speculum. Lid specula increase risks of complications, create more discomfort for the patient and are additional interference in a constrained space requiring significant precision for a successful procedure. The discomfort caused by the high profile apparatus is especially pronounced for patients with narrow lids (see ¶¶ 7 & 8, above). The criss-cross channels solve this problem, which is a real problem, because they create a low profile that can fit under a patient's lid.

10. The X-Y translation capability built in to the eye fixation apparatus, (claims 3-10 and 14-21) and the use of docking screws rather than conventional pincers (claims 5,6, 9, 10, 16, 17, 20 and 21), are also major improvements over the state of the art. The X-Y adjustment capability allows the laser or other surgical apparatus to be slaved to the eyeball, rather than vice versa (e.g. as shown in the Curtis reference, cited by Examiner). Use of translation rods with adjustment knobs, directly on the eye fixation device, greatly reduces the manual dexterity required for adjustments, and provides for more accurate docking of the surgical apparatus. The improvement has been significant, especially in Femtosecond procedures, in achieving superior centration properties.

a. The X-Y translation capability and use of docking screws provides other advantages as well. No fixation device will achieve perfect alignment on a patient's eye. Existing eye fixation devices, represented by Hellenkamp, Curtis and L'Esperance, don't adjust to the eyeball, so surgeons either have to force the eye into alignment by manipulation of the fixation apparatus or, in the case of Femtosecond laser surgery, the laser controls must provide for complicated adjustment capabilities to compensate for x-y offset. Forcing the eye into alignment by manually distorting the fixation apparatus magnifies all of the problems with eye distortion discussed above. Attempting to correct for gross distortions through laser controls requires complicated hardware and software which is expensive and potentially prone to problems. In addition, for microkeratome procedures no adjustment is possible without the x-y

translation capability. The only adjustment provided is for depth of the blade.

b. The x-y translation capability of claims 3-10 and 14-21 allows the surgeon to dock the laser or other apparatus into the fixation device, and make simple adjustments using the docking screws (claims 5,6, 9, 10, 16, 17, 20 and 21) while sighting to an eye with minimal distortions.

c. The addition of adjustment arms, as in claims 2, 13 and 22 allow a surgeon to easily maneuver the device on the eye surface without their fingers obscuring their vision. Additionally, because the surgeon's fingers are holding the adjustment arms – i.e. away from the actual conjunctival surface – there is less chance of scratches or contamination due to inadvertent contact.

11. The experience of myself and my staff has demonstrated the need for these improvements. One must appreciate that ophthalmologic surgery using lasers to reshape the eye, or perform other procedures, frequently involves adjustments in the sub-micron range, so seemingly minor improvements to surgical apparatus can produce significant improvements in patient outcomes and economies. I would not have expended the time, effort and money to develop this new invention if existing devices were fully adequate and did not exhibit known adverse affects upon tissue health and healing during refractive eye surgery procedures..

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED THIS B R Will January 12, 2007

BRIAN R. WILL, MD

Residence: Vancouver, WA
Citizenship: United States of America
Post Office address: 8100 NE Parkway Dr.
Vancouver, WA 98662

CLINICAL AND EXPERIMENTAL
OPTOMETRY

ORIGINAL PAPER

Dry eye after LASIK: Comparison of outcomes for Asian and Caucasian eyes

Clin Exp Optom 2005; 88: 2: 89–96

Julie M Albietz* BAppSc(Optom)(Hons) PhD
Lee M Lenton† MBBS FRANZCO FRACS
Suzanne G McLennan† BAppSc(Optom)
* Queensland University of Technology, Brisbane, Australia
† Brisbane, Australia

Submitted: 12 January 2004
Revised: 29 November 2004
Accepted for publication: 1 December 2004

Background: Dry eye is a common complication of LASIK surgery. Our clinical impression was that post-LASIK dry eye was more problematic for our Asian patients. The aim of this study was to determine if dry eye after LASIK is more prevalent, more sustained and more severe in Asian eyes compared with Caucasian eyes.
Methods: This study was based on a retrospective analysis of a clinical database. Data (n = 932 eyes, 932 patients) was collected before and after (week 2 and months 1, 3 and 6) LASIK surgery. Patients were defined as Asian if both parents were of East Asian ethic origin. Assessments included dry eye symptoms, ocular surface staining, tear volume, tear secretion, tear film stability and corneal sensation.
Results: Asian eyes had greater ocular surface staining, poorer tear film stability and lower tear volume before LASIK and at all times after LASIK. Dry eye symptoms occurring 'often or constantly' were more prevalent at all time points after LASIK in Asian eyes. Chronic dry eye persisting six months or more after LASIK was diagnosed in 28 per cent of Asian eyes and 5 per cent of Caucasian eyes ($p < 0.001$). Asian patients with chronic dry eye were predominantly female, reported dry eye symptoms, had greater ocular surface staining and lower tear secretion, stability and volume before surgery. After LASIK, Asian eyes had a slower return to pre-operative values for ocular surface staining, tear volume and corneal sensation.
Discussion: The risk of chronic dry eye after LASIK was significantly higher in Asian eyes. Contributing factors could include racial differences in eyelid and orbital anatomy, tear film parameters and blinking dynamics and higher attempted refractive corrections in Asian eyes.

Key words: Asian eye, dry eye, LASIK, myopia

Dry eye preventing safe and comfortable contact lens wear is a major motivating factor for patients considering refractive surgery.[1] Dry eye is considered by refractive surgeons to be the most common complication of LASIK surgery.[2] Cutting a LASIK flap and performing a stromal ablation disrupts the corneal innervation and produces a relative loss of corneal sensation for up to six months after surgery.[3-6] This loss of corneal sensation appears to be a significant contributing factor to the reduction in tear secretion, tear film stability, tear clearance, blink rate, conjunctival goblet cell density and the increase in tear osmolarity and punctate epitheliopathy of the post LASIK eye.[4,6-11] In patients with dry eye before LASIK,[11] in long-term contact lenses wearers[4,9] and in those having deeper surgical ablations[5] and superior hinged flaps,[6] the return of corneal sensation to levels observed before surgery appears to take longer than six months and is associated with more persistent dry eye signs and symptoms.[4,6,9]

Recent studies[12-14] have suggested that dry eye is more prevalent in Asian

populations than in Caucasians. Clinically, we had formed the impression that sustained dry eye after LASIK was more common in our Asian patients. This observation was of concern to us as the prevalence of myopia is much higher in Asians than in Caucasians[15,16] and appears to be increasing in urbanised Asian communities.[17] LASIK continues to be the dominant refractive surgery procedure for myopia,[18] therefore it is likely that increasing numbers of myopic Asians will seek refractive surgery. In this study, we analysed our clinical patient database to compare Asian and Caucasian patients after LASIK. The aims of the analysis were to determine if dry eye after LASIK is more prevalent, more severe and more sustained in Asian eyes.

METHODS

The study was a retrospective analysis of 932 patients who underwent LASIK for correction of myopia and myopic astigmatism at Excimer Laser Vision Centre, Brisbane, Australia, between August 1998 and December 2002. Our database tracks surgical outcomes for all myopic LASIK procedures and contained a total of 1,886 LASIK procedures, of which 1,846 were primary LASIK procedures on 1,026 patients. Of these, 932 patients met the inclusion criteria and had complete data for at least one eye for 12 months. Data analysis was based on these 932 patients. In patients who had surgery on both eyes, only the right eye data were analysed, provided the data were complete and the inclusion criteria were met. All patients received a detailed explanation of the procedures involved in the study and provided written informed consent. The Queensland University of Technology Human Research Ethics Committee provided written approval of the study protocol.

The eligibility criteria used in the study were:

- no autoimmune disease, metabolic disease or uncontrolled systemic disease
- no active disease of the external eye or adnexae
- no intraocular disease
- no degenerative or neurotrophic corneal disease
- no pre-operative or post-operative use of topical medications other than those prescribed
- no previous ocular surgery or trauma
- not pregnant or breastfeeding
- stable refraction for at least 12 months prior to LASIK
- stable keratometry and pachymetry following cessation of contact lens wear
- no lenticular opacities identified before or after surgery that were deemed to have a significant effect on the refractive outcome
- compliance with prescribed tear film and ocular surface management before and after surgery.

Patients were defined as Asian if one or both parents were of East Asian ethic origin (for example, Chinese, Japanese, Thai, Filippino, Vietnamese, Korean, Taiwanese, Singaporean, Malaysian). To avoid complicating the analysis, we excluded patients who had partial Asian ancestry. We also excluded patients of Indian Asian ancestry.

Pretreatment of the tear film and ocular surface was performed on indication where specific tear film and ocular surface problems were identified before LASIK. Pre-treatment measures included:

1. Non-preserved artificial tears, gels or ointments; non-preserved steroid (prednisolone sodium phosphate 0.5 per cent or 1 per cent hydrocortisone ointment) for ocular surface inflammation and/or eyelid margin inflammation.
2. Silicone punctal plugs (Flexplug, Eagle Vision, Memphis USA) for tear deficiency, where artificial lubricants alone were insufficient.
3. Lid hygiene procedures for eyelid disease.

All LASIK procedures were performed by one experienced LASIK surgeon (LL) using a surgeon-adjusted ablation nomogram. The lamellar flaps were created using the automatic corneal shaper (Chiron Vision, Irvine, USA) and the excimer laser (Nidek EC-5000, Nidek, Gamagori, Japan) performed the stromal ablations. The flaps were 8.5 mm wide and 130 µm thick with an optic zone of 5.5 to 6.5 mm and a transition zone of 7.5 mm. After surgery, all eyes received a standard treatment of non-preserved chloramphenicol 0.5 per cent (Chauvin Pharmaceuticals, Essex, UK) four times per day for three days and fluorometholone acetate 0.1 per cent (Flucon, Alcon Laboratories, Fort Worth USA) four times per day, tapering one drop per week over one month. All patients were instructed to use non-preserved artificial tears (Cellufresh [sodium carboxymethylcellulose 0.5 per cent in lactate buffer, non-preserved, Allergan, Irvine USA] and/or Bion Tears [hydroxypropyl methylcellulose 0.3 per cent, Dextran 70 0.1 per cent in bicarbonate buffer, Alcon Laboratories, Fort Worth USA]) at least every two hours for the first month after surgery and then at least four times per day for the 12 months after surgery.

Patients were also instructed to use sodium carboxymethylcellulose 1.0 per cent in lactate buffer, non-preserved (Celluvisc, Allergan, Irvine USA) for at least one week after LASIK as a night-time lubricant and, if long-term night-time lubrication was required, then Celluvisc or carbomer gel, non-preserved (Polygel, Alcon Laboratories, Fort Worth USA) or paraffin plus lanolin, non-preserved ointment (Polyvisc, Alcon Laboratories, Fort Worth USA) were prescribed. Silicone punctal plugs were inserted in the inferior puncta of tear deficient eyes non-responsive to the lubricant therapy described above.

Assessments

The following assessments were performed on each patient before surgery and at two weeks, and one, three and six months post-LASIK with the results recorded in the clinical database:

1. **Fluorescein break-up time** (FBUT): a measure of tear film stability, was performed using the method described by Cho and Brown.[19]
2. **Schirmer I test** (Colorbar, Eagle Vision, Memphis USA): a measure of reflex tear secretion was performed without anaesthetic using standard methods.[20] The Schirmer test was not performed at week 2 to avoid interference with flap healing.
3. **Phenol red thread tear test** (PRT) (Zone Quick Menicon Co Ltd, Nagoya Japan): a measure of tear secretion, volume and turnover was performed using the methods previously described.[21]

Nationality	Number of subjects (n = 54 total)
Chinese	25
Vietnamese	7
South Korean	6
Indonesian	5
Japanese	4
Taiwanese	2
Singaporean	2
Malaysian	2
Filippino	1

Table 1. Nationality of ancestry in Asian patient group

4. **Ocular surface staining**: fluorescein ocular surface staining was graded by the Oxford grading scheme on a scale of zero to five using methods previously described.[22]
5. **Corneal sensation**: central corneal sensation was measured using the Cochet-Bonnet aesthesiometer (Luneau Ophthalmologie, Charters, France).[23]
6. **Dry eye symptoms**: dry eye symptoms were assessed using the McMonnies Dry Eye Symptom Survey, a validated dry eye symptom survey.[24] Patients were classified as having dry eye symptoms (either before or after surgery) if they reported experiencing one or more of the primary symptoms in the survey (soreness, scratchiness, dryness, grittiness, burning) occurring often or constantly.
7. **Refractive outcome**: defined as the difference between the spherical equivalent refraction and the target spherical equivalent refraction.

Patients were questioned on their history of contact lens wear. Patients were classified as contact lens wearers before surgery, if they wore lenses on a regular basis (minimum average wearing time of 30 hours per week) and had worn contact lenses for at least the past year. Occasional or intermittent contact lens wearers were regarded as non-contact lens wearers for the purpose of this study.

In accordance with standard criteria,[20] patients were diagnosed as having dry eye before or after surgery, if they experienced one or more of the McMonnies dry eye primary symptoms occurring 'often' or 'constantly', their FBUT was less than 10 seconds and they had a fluorescein corneal staining score of one or more. Patients were diagnosed as having chronic dry eye if they had dry eye (according to the definition above) for a period of six months or more after surgery. The six-month cut-off point was chosen because at six months, the majority of studies indicate that dry eye parameters such as dry eye symptoms,[8] tear film stability,[8,10] ocular surface staining,[8,9] tear volume,[8] tear secretion[9,10] and corneal sensation[3-6] have returned to pre-operative levels.

Statistical analysis

Parametric tests were used to analyse refractive data. Other ocular variables were analysed using non-parametric tests because of the non-normal distribution of the data. Comparisons between groups and between variables were made using the Pearson Chi Square Test for categorical data and the ANOVA or the Kruskall-Wallis ANOVA tests for continuous data. Differences were considered significant when $p < 0.05$.

RESULT

Overall patient demographics

For the 932 patients, the mean spherical equivalent refraction was -4.6 ± 2.8 D (sphere -3.78 ± 2.19 D [minimum -1.00; maximum -16.50], cylinder -0.68 ± 0.91 D [minimum 0.00; maximum -6.50]). Mean ablation depth for all patients was 59 ± 27 µm (minimum 15; maximum 161).

Mean patient age was 36 ± 9 years (minimum 18; maximum 65) and 56 per cent (522/932) of patients were female. Before LASIK surgery five per cent (47/932) of the patients were diagnosed with dry eye and a further 16 per cent (151/932) reported dry eye symptoms but did not have significant dry eye signs. Following surgery, seven per cent (65/932) of patients were affected by chronic dry eye.

Comparison of patient characteristics: Asian and Caucasian groups

Asian patients comprised six per cent (54/932) of patients. Chinese patients formed 46 per cent of the Asian group. The breakdown of nationalities of the Asian patients is given in Table 1. Patient characteristics for Asian and Caucasian patients are presented in Table 2. The Asian group had significantly more females, higher attempted refractive corrections and greater total ablation depths compared to the Caucasian group. There were significantly more contact lens wearers in the Asian group. The percentage of subjects diagnosed with dry eye before surgery and the percentage receiving pretreatment was not significantly different between the groups.

Comparison of intra-operative and post-operative complications and refractive outcomes: Asian and Caucasian groups

There were no significant differences between Asian and Caucasian eyes with respect to intra-operative and post-operative complications (Table 3). The difference between the spherical equivalent of refraction and the target refractive outcome was not significantly different between Asian and Caucasian eyes at any time after surgery.

Comparison of chronic dry eye prevalence after LASIK

Asians eyes had a higher prevalence of chronic dry eye after LASIK (28 per cent [15/54] compared with five per cent [41/878] for Caucasian eyes, [$p < 0.001$]). Asian patients with chronic dry eye were predominantly female, reported dry eye symptoms, had greater ocular surface staining and poorer tear secretion, tear film stability and tear volumes before surgery (Table 4).

Comparison of dry eye outcomes in Asian and Caucasian groups matched for surgical ablation depth

To eliminate bias in the results due to the Asian patients having a greater pre-operative myopic correction and therefore greater total ablation depth compared to

the Caucasians, we examined a subgroup of patients where the Asian (n = 48) and Caucasian (n = 407) patients were matched for surgical ablation depth. The subject demographics of this subgroup are given in Table 5. With this adjustment for refractive ablation, the prevalence of chronic dry eye was 25 per cent (12/48) in Asian eyes and seven per cent (29/407) in Caucasian eyes. Comparisons of the prevalence of dry eye symptoms and of tear film and ocular surface parameters before and after surgery for the surgical ablation depth matched Asian and Caucasian groups are given in Table 6.

Before LASIK, there were no significant differences in the percentages of patients in the Asian and Caucasian groups reporting dry eye symptoms often or constantly. Dry eye symptoms were significantly more prevalent in Asian eyes at all times after surgery. Tear film stability and volume were significantly reduced before surgery and at all times after surgery in Asian eyes. Ocular surface fluorescein staining was greater in Asian eyes before surgery and at all times after surgery. Compared with Caucasian eyes, tear secretion was significantly reduced at one month and three months after surgery in the Asian group. Central corneal sensation was significantly reduced in Asian eyes at three and six months compared with Caucasian eyes.

Asian eyes had a slower recovery to pre-operative values for some of the pre-operative dry eye parameters (Table 6). In Asian eyes, dry eye symptoms were more prevalent compared to pre-operative values at all times after surgery. In Caucasian eyes, the prevalence of dry eye symptoms was significantly increased at months 1, 3 and 6 after surgery compared to pre-operative values. Ocular surface staining was significantly increased at all times after surgery in Asian eyes but increased only at week 2 after surgery in Caucasian eyes. The PRT test was significantly reduced from pre-operative values at week 2 in Caucasian eyes and week 2, month 1 and month 3 in Asian eyes. Corneal sensation recovered to pre-operative levels by month 6 in Caucasian eyes whereas in the Asian group the recovery of corneal sensation did not occur until month 12.

Variable	Asian n = 54 (6%)	Caucasian n = 878 (94%)	*p* value*
Age ± SD (years)	34 ± 8	36 ± 9	NS§
% Female	73	55	p = 0.006
Attempted spherical equivalent correction ± SD (D)	-5.32 ± 2.28	-4.00 ± 2.23	p < 0.001
Attempted spherical correction ± SD (D)	-5.21 ± 2.23	-3.60 ± 2.26	p <0.01
Attempted cylinder correction ± SD (D)	-0.77 ± 0.73	-0.89 ± 0.95	NS
Ablation depth ± SD (μm)	76 ± 29	58 ± 26	p < 0.001
Mean pre-op keratometry ± SD (D)	44.69 ± 1.68	44.60 ± 1.93	NS
% Contact lens wear pre-op	95	78	p = 0.002
% Soft lens wearers	92	94	NS
Length of time wearing contact lens ± SD (years)	11 ± 9	11 ± 8	NS
% Diagnosed with dry eye	28	25	NS
% Receiving pre-treatment	37	30	NS

* Based on a comparison between Asian and Caucasian groups
§ NS = not significant at the 5% level

Table 2. Comparison of pre-operative demographics and tear film and ocular surface variables in Asian and Caucasian eyes (all subjects included)

Variable	Asian n = 54	Caucasian n = 878	*p* value*
Incomplete flap	0	1 (0.1%)†	NS§
Intra-operative epithelial defect	2 (3.6%)	31 (3.5%)	NS
Complete flap	0	1 (0.1%)	NS
Interface inflammation (grade 1-2)	6 (10.7%)	90 (10.3%)	NS
Interface inflammation (grade 3-4)	0	11 (1.3%)	NS
Epithelial ingrowth	0	10 (1.1%)	NS
Loss of best corrected acuity of ≥ 1 line	0	1 (0.1%)	NS

* Based on a comparison between Asian and Caucasian groups
† Number of subjects experiencing the complication
§ NS = not significant at the 5% level

Table 3. Comparison of inter-operative and post-operative complications in Asian and Caucasian eyes

DISCUSSION

To our knowledge, this is the first study that directly compares LASIK outcomes in Asian and Caucasian eyes. This study has demonstrated that Asian patients have a significantly increased risk of experiencing chronic dry eye after LASIK. It also suggests that the dry eye after LASIK is more severe and more sustained in Asian compared to Caucasian patients. These findings are due, at least in part, to Asian eyes having higher myopic corrections and therefore requiring greater refractive

Pre-operative variable	Asian patients with chronic dry eye n = 15 (28%)	Asian patients no chronic dry eye n = 39 (72%)	*p* value*
% Female	87	68	p = 0.05
Age ± SD (years)	33 ± 9	34 ± 8	NS§
Pre-operative spherical equivalent of refraction ± SD (D)	-5.59 ± 1.81	-5.78 ± 2.38	NS
Total ablation depth ± SD (µm)	75 ± 26	80 ± 30	NS
% Contact lens wear	88	95	NS
Duration of contact lens wear ± SD (years)	11 ± 8	13 ± 8	NS
% Dry eye symptoms	38	11	p = 0.002
Schirmer 1 test ± SD (mm/5 mins)	8 ± 4	16 ± 8	p = 0.01
PRT test ± SD (mm/15 s)	15 ± 8	18 ± 7	p = 0.02
FBUT ± SD (s)	4 ± 3	7 ± 3	p = 0.04
Corneal sensation ± SD (mm)	5.3 ± 1.3	5.6 ± 1.1	NS
Staining score ± SD	1.3 ± 2.5	0.1 ± 0.3	p = 0.002

* Based on a comparison between Asian patients with and without chronic dry eye
§ NS = not significant at the 5% level

Table 4. Association of chronic dry eye after LASIK in Asian eyes with pre-operative variables

Pre-operative variable	Asian n = 48	Caucasian n = 407	*p* value*
% Female	74	60	p = 0.04
Age ± SD (years)	35 ± 8	36 ± 9	NS§
Pre-operative spherical equivalent of refraction ± SD (D)	-5.62 ± 2.25	-5.66 ± 2.07	NS
Total ablation depth ± S (mm)	77 ± 29	78 ± 21	NS
% Contact lens wear	90	89	NS
Length of time in contact lens wear ± SD (years)	11 ± 7	12 ± 9	NS
% Diagnosed with dry eye	27%	22%	NS

* Based on a comparison between Asian and Caucasian groups
§ NS = not significant at the 5% level

Table 5. Patient demographics of ablation depth matched Asian and Caucasian subgroups

ablations to achieve emmetropia. We have previously demonstrated deeper stromal ablations to be a risk factor for chronic dry eye after myopic LASIK.[25] Deeper stromal ablations result in a slower return of corneal sensation to levels observed before surgery.[5,26] This loss of sensory innervation has been identified as one of the leading causes of tear film and ocular surface anomalies after LASIK surgery.[3,7,9,27]

After controlling for surgical ablation depth, other pre-operative characteristics of our Asian group could predispose this group to a higher likelihood of developing chronic post-LASIK dry eye. The Asian group had significantly more females, more contact lens wearers, lower pre-operative tear volume, less tear film stability and greater pre-operative ocular surface staining scores compared to the Caucasian group. All of these factors have been associated with a delayed recovery of corneal sensation to pre-operative levels.[4,5,9,11,25] Indeed, corneal sensation was decreased in the Asian group compared to the Caucasian group at all times, with these differences being significant at months 3 and 6 after surgery.

Additionally, anatomical differences between the Asian and Caucasian eye may produce a more severe and sustained post-LASIK dry eye. The prevalence of dry eye symptoms and diagnosed dry eye in the general population appears to be greater in Asians than in Caucasians. For example, the dry eye prevalence determined by diagnostic criteria of chronic dry eye symptoms, ocular surface staining and tear film instability or insufficiency in Japanese patients presenting to an ophthalmology clinic was 17 per cent.[28] Australian and Danish studies using similar dry eye diagnostic criteria to the Japanese study gave dry eye prevalence of 11 per cent and eight per cent, respectively.[29,30] Self-reporting of one or more dry eye symptoms experienced often or all the time occurred in 33 per cent of 598 Japanese patients[31] and 18 per cent of 1,548 Australian subjects.[29]

In elderly patients (65 years or older), dry eye symptoms are also more prevalent in Asian participants. The prevalence of self-reported dry eye symptoms occurring often or constantly was 34 per cent in 1,361 elderly Taiwanese residents[32] and 15 per cent in 2,420 elderly US residents.[33] A large scale study involving nearly 39,876 participants in the US Women's Health Study aged 45 to 84 years, determined that compared to Caucasians, Asian participants were more likely to report severe dry eye symptoms (odds ratio 1.77, confidence interval 1.17-2.69).[34] While several authors have commented on the greater prevalence of dry eye in Asian eyes, they have been unable to offer any real explanation other than to state that the differences may be due to racial and/or environmental

factors and that further research is required.[32,34]

Few published studies have compared dry eye parameters between Asian and Caucasian subjects. Cho and Brown[19] found that Asians (Hong Kong Chinese) had significantly lower FBUT (mean eight seconds) compared to 11 to 15 seconds for Caucasian eyes. These researchers attributed the lower tear film stability in Asian eyes to differences in the eyelid anatomy and their interactions with the tear film.[19] No significant differences in tear volume measured by the PRT test were found between young normal non-contact lens wearing Asian (Japanese) and Caucasian (US) eyes, although the Japanese group had a lower mean PRT test value (18.8 ± 8.6) versus. (23.9 ± 9.5).[35] We also found that our Asian patients had significantly lower PRT and FBUT than our Caucasian patients at all times before and after surgery.

Blink rates and completeness of blinking can significantly affect tear film dynamics and ocular surface health.[20,29] Differences in blink rates between Asian and Caucasian eyes have not been evaluated but it is our observation that our Asian patients, both before and after surgery, have a lower blink rate and a greater tendency to incomplete blinking. This would produce the characteristic band of inferior staining observed in our Asian patients with chronic post-LASIK dry eye (Figures 1 and 2).

We feel that the blinking and lid surfacing anomalies observed in Asian eyes are due to anatomical differences in the eyelid and orbit, possibly exacerbated by long-term contact lens wear, which is acknowledged to cause blinking anomalies,[20] and the delayed return to pre-operative values for corneal sensation in Asian eyes. Toda and colleagues[10] found that blink rates after LASIK were reduced at months 3, 6 and 12 after LASIK in their Japanese subject group. To date, no published study has evaluated blink rate in Caucasians after LASIK. Therefore, further studies to compare blink rates in Asians and Caucasians before and after LASIK are warranted.

Surgical trauma when cutting the flap is another potential factor contributing to

Dry eye assessments	Time from surgery	Asian n = 48	Caucasian n = 407	*p* value*
% Dry eye symptoms	Pre-op	23	20	NS†
	Week 2	51‖	29	p < 0.001
	Month 1	50‖	32‖	p = 0.007
	Month 3	48‖	38‖	p = 0.04
	Month 6	55‖	39‖	p = 0.001
	Month 12	43‖	29	p = 0.009
FBUT ± SD (seconds)	Pre-op	6 ± 3	8 ± 4	p = 0.02
	Week 2	3 ± 3§	6 ± 3§	p = 0.02
	Month 1	3 ± 3§	6 ± 3§	p = 0.06
	Month 3	4 ± 3	6 ± 5	p = 0.03
	Month 6	4 ± 3	7 ± 3	p = 0.02
	Month 12	4 ± 2	7 ± 5	p = 0.006
PRT ± SD (mm/15s)	Pre-op	17 ± 8	20 ± 8	p = 0.01
	Week 2	14 ± 7§	16 ± 8§	p = 0.04
	Month 1	12 ± 9§	18 ± 7	p = 0.003
	Month 3	13 ± 5§	18 ± 8	p = 0.006
	Month 6	16 ± 8	19 ± 8	p = 0.06
	Month 12	19 ± 7	24 ± 8	p = 0.005
Schirmer 1 ± SD (mm/5 min)	Pre-op	15 ± 8	16 ± 8	NS
	Month 1	6 ± 8§	11 ± 8§	p = 0.009
	Month 3	9 ± 5§	12 ± 11§	p = 0.03
	Month 6	13 ± 8	15 ± 10	NS
	Month 12	14 ± 10	16 ± 11	NS
Staining score ± SD	Pre-op	0.5 ± 1.5	0.3 ± 1.0	p = 0.04
	Week 2	1.7 ± 3.0‖	0.6 ± 1.8‖	p < 0.001
	Month 1	1.1 ± 2.7‖	0.5 ± 1.7	p = 0.008
	Month 3	0.9 ± 1.8‖	0.5 ± 1.7	p = 0.03
	Month 6	1.1 ± 1.9‖	0.4 ± 1.4	p = 0.005
	Month 12	1.0 ± 2.1‖	0.4 ± 1.4	p < 0.001
Corneal sensation ± SD (mm)	Pre-op	5.3 ± 0.6	5.4 ± 1.0	NS
	Week 2	0.3 ± 1.6§	0.5 ± 1.8§	NS
	Month 1	1.0 ± 1.9§	1.1 ± 2.0§	NS
	Month 3	2.2 ± 2.1§	3.4 ± 2.0§	p = 0.03
	Month 6	3.8 ± 2.0§	4.9 ± 1.8	p = 0.04
	Month 12	4.7 ± 2.1	5.1 ± 1.5	NS

* Based on a comparison between Asian and Caucasian patient groups
† NS = not significant at the 5% level
‖ Significantly increased (at the 5% level) from pre-operative value
§ Significantly decreased (at the 5% level) from pre-operative value

Table 6. Comparison of dry eye assessments before and after myopic LASIK surgery in Asian and Caucasian groups matched for pre-operative refractive target and total laser ablation depth

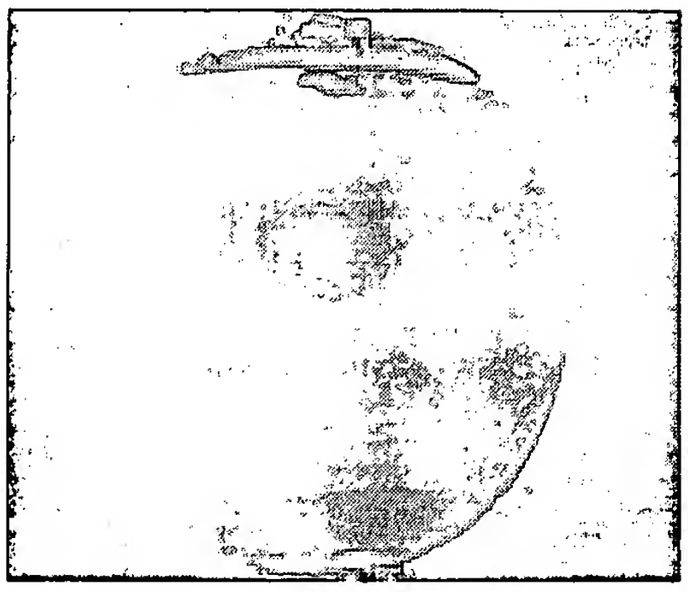


Figure 1. Chronic LASIK dry eye in a female Asian patient at nine months post LASIK for -11 D myopic correction. There is significant inferior punctate epitheliopathy and a less severe band of staining superior to the central ablation zone.

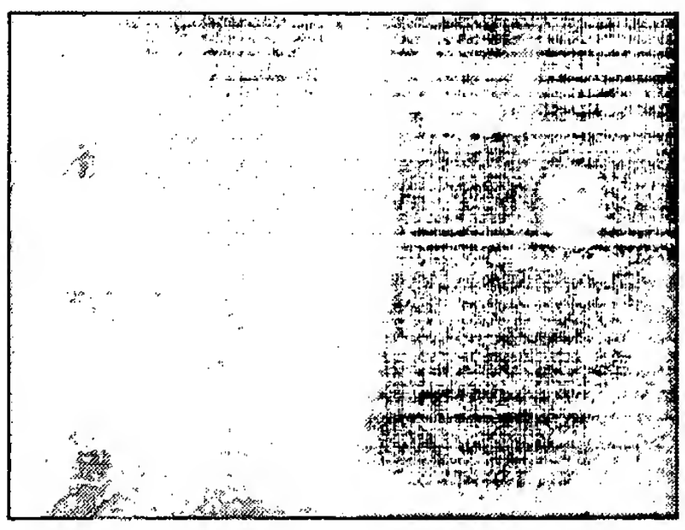


Figure 2. Significant inferior punctate epitheliopathy in an Asian eye with inferior entropion and trichiasis one month post-LASIK. Contact lens wear before surgery masked the condition.

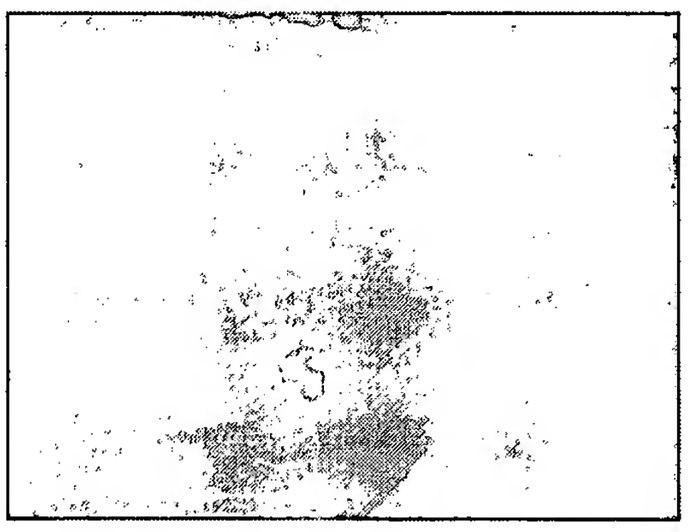


Figure 3. Diffuse staining in a female Asian patient at week 2 after LASIK for -6 D myopic correction. The patient had not been using post-operative lubrication routinely.

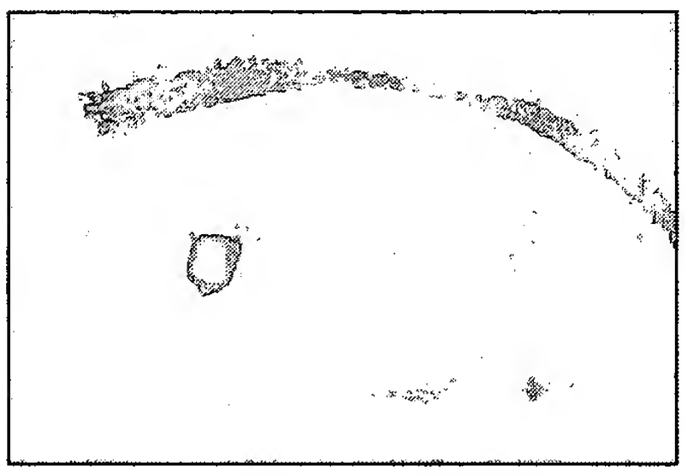


Figure 4. Superior entropion and trichiasis masked by contact lens wear in a pre-operative LASIK candidate. The patient was advised to remain in contact lenses or consider entropion repair prior to undergoing any form of keratorefractive surgery.

ocular surface damage and dry eye after LASIK.[36] In general, Asian eyes have a shallower orbit, smaller vertical orbital dimensions and differences in the upper eyelid anatomy compared to Caucasians. Asian eyes also have narrower palpebral fissures.[37,38] These factors can predispose Asian eyes to greater likelihood of flap cut problems.[38] Asano-Kato and co-workers[39] found that Asian eyes were more disposed to problems with suction with the microkeratome. They concluded that the narrow palpebral fissures commonly found in Asian populations might be a risk factor for insufficient fixation of a microkeratome in LASIK. Although our Asian patients did not experience a higher incidence of flap cut complications, our surgeon did find that intra-operative preparation for the flap cut took longer for Asian eyes compared with Caucasian eyes, due to these eyelid and orbital issues. Longer intra-operative times and a tight fit with the suction ring and keratome, even in the absence of flap cut complications, could add to the intra-operative damage to the ocular surface and the perilimbal goblet cell loss and be a contributing factor to the high degree of ocular surface staining seen after LASIK in Asian patients (Figure 3).

Epiblepharon and entropion can be features of Asian eyelids and, in severe cases, are associated with trichiasis and corneal punctate epithelial erosions.[37] Contact lens wear will mask the effects of trichiasis (Figures 4) and these patients may need to consider eyelid surgery to correct the eyelid anomalies before LASIK if significant trichiasis and punctate erosions are present, or alternatively remain in their contact lenses if ocular health permits.

The greater prevalence, duration and severity of dry eye in our Asian group is concerning, particularly given that we employ intensive ocular surface management strategies before, during and after surgery in an attempt to reduce the incidence and severity of LASIK induced dry eye,[8,25,36] and given that the prevalence and severity of myopia in Asian eyes is increasing. Asian LASIK candidates with increased risk of developing dry eye (females, dry eye before surgery, higher attempted corrections and long-term contact lens wearers) should be counselled pre-operatively regarding their increased risk of developing chronic dry eye after LASIK and alternative corrective options should be considered. It may be prudent for Asian patients who are safely and comfortably wearing contact lenses to remain in their contact lenses or to consider photorefractive keratectomy which has a lower long-term incidence of chronic dry eye symptoms and signs.[1,7,10]

Grants: None

Conflict of interest: The authors have no commercial or proprietary interest in any of the products or companies referred to in the article.

REFERENCES

1. Toda I, Yagi Y, Hata S, Itoh S, Tsubota K. Excimer laser photorefractive keratectomy for patients with contact lens intolerance caused by dry eye. *Br J Ophthalmol* 1996; 80: 604-609.
2. Solomon KD, Holzer MP, Sandoval HP. Refractive surgery survey 2001. *J Cataract Refract Surg* 2002; 28: 346-355.
3. Linna TU, Vesaluoma MH, Perez-Santonja JJ, Petroll WM, Alio JL, Tervo TM. Effect of myopic LASIK on corneal sensitivity and morphology of subbasal nerves. *Invest Ophthalmol Vis Sci* 2000; 41: 393-397.
4. Benitez-del-Castillo JM, del Rio T, Iradier T, Hernandez JL, Castillo A, Garcia-Sanchez J. Decrease in tear secretion and corneal sensitivity after laser *in situ* keratomileusis. *Cornea* 2001; 20: 30-32.
5. Nassaralla BA, McLeod SD, Nassaralla JJ Jr. Effect of myopic LASIK on human corneal sensitivity. *Ophthalmology* 2003; 110: 497-502.
6. Donnenfeld ED, Solomon K, Perry HD, Doshi SJ, Ehrenhaus M, Solomon R, Biser S. The effect of hinge position on corneal sensation and dry eye after LASIK. *Ophthalmology* 2003; 110: 1023-1029.
7. Lee JB, Ryu CH, Kim J, Kim EK, Kim HB. Comparison of tear secretion and tear film instability after photorefractive keratectomy and laser *in situ* keratomileusis. *J Cataract Refract Surg* 2000; 26: 1326-1331.
8. Albietz JM, Lenton LM, McLennan SG. The effect of tear film and ocular surface management on myopic LASIK outcomes. In: Sullivan D, Stern ME, Tsubota K, Dartt DA, Sullivan RM, Bromberg BB, eds. Lacrimal Gland Tear Film and Dry Eye Syndromes 3. New York, NY: Klulwer Academic/ Plenum Publishers, 2002; 711-726.
9. Battat L, Macri A, Dursun D, Pflugfelder SC. Effects of laser *in situ* keratomileusis on tear production clearance, and the ocular surface. *Ophthalmology* 2001; 108: 1230-1235.
10. Toda I, Asano-Kato N, Komai-Hori Y, Tsubota K. Dry eye after laser *in situ* keratomileusis. *Am J Ophthalmol* 2001; 132: 1-7.
11. Toda I, Asano-Kato N, Hori-Komai Y, Tsubota K. Laser-assisted *in situ* keratomileusis for patients with dry eye. *Arch Ophthalmol* 2002; 120: 1024-1028.
12. Lin PY, Tsai SY, Cheng CY, Liu JH, Chou P, Hsu WM. Prevalence of dry eye among an elderly Chinese population in Taiwan: the Shihpai Eye Study. *Ophthalmology* 2003; 110: 1096-1101.
13. Schaumberg DA, Sullivan DA, Buring JE, Dana MR. Prevalence of dry eye syndrome among US women. *Am J Ophthalmol* 2003; 136: 318-326.
14. Lee AJ, Lee J, Saw SM, Gazzard G, Koh D, Widjaja D, Tan DT. Prevalence and risk factors associated with dry eye symptoms: a population based study in Indonesia. *Br J Ophthalmol* 2002; 86: 1347-1351.
15. Kleinstein RN, Jones LA, Hullett S, Kwon S, Lee RJ, Friedman NE, Manny RE, Mutti DO, Yu JA, Zadnik K. Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error Study Group. Refractive error and ethnicity in children. *Arch Ophthalmol* 2003; 121: 1141-1147.
16. Voo I, Lee DA, Oehrich FO. Prevalence of ocular conditions among Hispanic, white, Asian and black immigrant students examined by the UCLA Mobile Eye Clinic. *J Am Optom Assoc* 1998; 69: 255-261.
17. Lin LL, Shih YF, Hsiao CK, Chen CJ, Lee LA, Hung PT. Epidemiologic study of the prevalence and severity of myopia among school children in Taiwan in 2000. *J Formos Med Assoc* 2001; 100: 684-691.
18. Duffey RJ, Leaming D. US trends in refractive surgery: 2002 ISRS survey. *J Refract Surg* 2003; 19: 357-363.
19. Cho P, Brown B. Review of the tear break-up time and a closer look at the tear break-up time of Hong Kong Chinese. *Optom Vis Sci* 1993; 70: 30-38.
20. Lemp MA. Report on the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes. *CLAO J* 1995; 21: 221-232.
21. Tomlinson A, Blades KJ, Pearce EI. What does the Phenol Red Thread test actually measure? *Optom Vis Sci* 2001; 78: 142-146.
22. Bron AJ, Evans VE, Smith JA. Grading of corneal and conjunctival staining in the context of other dry eye tests. *Cornea* 2003; 22: 640-650.
23. Cochet P, Bonnet R. L'esthesie cornéene. *Clin Ophthalmol* 1960; 4: 3-27.
24. McMonnies CW. Key questions in a dry eye history. *J Am Optom Assoc* 1986; 57: 512-517.
25. Albietz JM, Lenton LM. Chronic dry eye and regression in myopic LASIK. *J Cataract Refract Surg* 2004; 30: 675-684.
26. Kim WS, Kim JS. Change in corneal sensitivity following laser *in situ* keratomileusis. *J Cataract Refract Surg* 1999; 25: 368-373.
27. Wilson SE. Laser *in situ* keratomileusis-induced (presumed) neurotrophic epitheliopathy. *Ophthalmology* 2001; 108: 1082-1087.
28. Hikichi T, Yoshida A, Fukui Y, Hamano T, Ri M, Araki K, Horimoto K, Takamura E, Kitagawa K, Oyama M, Danjo Y, Kondo S, Fujishima H, Toda I, Tsubota K. Prevalence of dry eye in Japanese eye centres. *Graefes Arch Clin Exp Ophthalmol* 1995; 233: 555-558.
29. Albietz JM. Prevalence of dry eye subtypes in clinical optometry practice. *Optom Vis Sci* 2000; 77: 357-363.
30. Bjerrum KB. Keratoconjunctivitis sicca and primary Sjögren's syndrome in a Danish population aged 30–60 years. *Acta Ophthalmol Scand* 1997; 75: 281-286.
31. Shimmura S, Shimazaki J, Tsubota K. Results of a population-based questionnaire on the symptoms and lifestyles associated with dry eye. *Cornea* 1999; 18: 408-411.
32. Lin PY, Tsai SY, Cheng CY, Liu JH, Chou P, Hsu WM. Prevalence of dry eye among an elderly Chinese population in Taiwan: the Shihpai Eye Study. *Ophthalmology* 2003; 110: 1096-1101.
33. Schein OD, Munoz B, Tielsch JM Bandeen-Roche K, West S. Prevalence of dry eye among the elderly. *Am J Ophthalmol* 1997; 124: 73-88.
34. Schaumberg DA, Sullivan DA, Buring JE, Dana MR. Prevalence of dry eye syndrome among US women. *Am J Ophthalmol* 2003; 136: 318-326.
35. Sakamoto R, Bennett ES, Henry VA, Paragina S, Narumi T, Izumi Y, Kamei Y, Nagatomi Y, Myanaga Y, Hamano H. The phenol red thread tear test: a cross-cultural study. *Invest Ophthalmol Vis Sci* 1997; 34: 3510-3514.
36. Lenton LM, Albietz JM. The effect of carmellose-based artificial tears on the ocular surface. *J Refract Surg* 1999; 15: S227-S231.
37. Bernardino CR, Rubin PAD. Asian Americans: Cultural and anatomical considerations for periocular surgery. *Int Ophthalmol Clin* 2003; 43: 151-171.
38. Yo C. Asian Americans: Myopia and refractive surgery. *Int Ophthalmol Clin* 2003, Fall; 43(4): 173-187.
39. Asano-Kato N, Toda I, Hori-Komai Y, Takano Y, Tsubota K. Risk factors for insufficient fixation of microkeratome during laser *in situ* keratomileusis. *J Refract Surg* 2002; 18: 47-50.
40. Albietz JM, McLennan SG, Lenton LM. Ocular surface management of photorefractive keratectomy and laser *in situ* keratomileusis. *J Refract Surg* 2003; 19: 636-644.

Author's address:
Dr Julie Albietz
Department of Optometry
Queensland University of Technology
Victoria Park Road
Kelvin Grove QLD 4059
AUSTRALIA

Efficacy and safety of LASIK in 10,052 eyes of 5081 myopic Chinese patients.

Auteurs : Lanping Sun, Guifen Liu, Yanjun Ren, Ji Li, Junhua Hao, Xia Liu, Yajuan Zhang

Langue : Eng.
Date : 10-10-2005
Journal : **Journal of refractive surgery (Thorofare, N.J. : 1995)** (1081-597X)
Release: J Refract Surg. ;21(5 Suppl):S633-5

Abstract:

PURPOSE:
To analyze the outcomes and incidence of postoperative complications in a large series of patients undergoing LASIK for myopia.

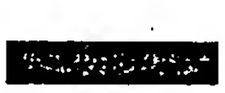
METHODS:
All 5081 patients (10,052 eyes) diagnosed with myopia at The Third Hospital of Handan, China, from September 2003 through March 2005 were studied. All study eyes underwent LASIK with 1-month follow-up. Spherical equivalent refraction, best spectacle-corrected visual acuity (BSCVA), and uncorrected visual acuity (UCVA) were measured before and after surgery and intra- and postoperative complications were recorded.

RESULTS:
Uncorrected visual acuity at 1-month follow-up of 9555 (95.1%) eyes reached or exceeded the preoperative BSCVA. Hemorrhage of corneal limbus during surgery occurred in 1060 (10.5%) eyes, Sands of Sahara syndrome occurred in 232 (2.3%) eyes, interface infection responsive to treatment occurred in 4 (0.04%) eyes, and epithelial ingrowth occurred in 1 (0.01%) eye.

CONCLUSIONS:
LASIK is a safe and effective method for the treatment of myopia.

Full text:
EBSCO - HTML (a besoin d'abonnement)
Ovid Technologies, Inc. - HTML (a besoin d'abonnement)
ProQuest Information and Learning - HTML (a besoin d'abonnement)

Sujets: Adult, China, Corneal Stroma, Equipment Safety, Female, Follow-Up Studies, Humans, Incidence, Intraoperative Complications, Keratomileusis, Laser In Situ, Male, Myopia, Postoperative Complications, Retrospective Studies, Treatment Outcome, Visual Acuity



RELATED PROCEEDINGS APPENDIX

There are no related proceedings.